

## **REMARKS-General**

By the above amendment, Applicant has amended the title to emphasize the novelty and better define the invention. The original patent title : Ultra-High Fiber Supplement And Method Of Weight And Cardiovascular Risk Reduction has been changed to :

ULTRA-HIGH FIBER SUPPLEMENT AND METHODS OF REDUCING WEIGHT,  
CARDIOVASCULAR RISKS, AND INGESTED TOXINS.

### **Explanation of Claims**

Claims 24 and 25 previously presented.

Claims 26-30 currently amended

Claims 31-33 previously presented

Claim 34 currently amended.

Claim 35 previously presented

Claims 36-41 currently amended

Claim 64 currently amended

claims 65-74 new claims based on breaking previously presented claim 37 into separate claims.

Applicant has been careful not to add new matter, and has provided direction to examiner by listing page numbers in original application to verify that information added was in original application.

**Applicant thanks examiner for phone conversations and assistance. Applicant very much appreciates time and advice given by examiners, and appreciates that examiners stated they would work with applicant after receiving the amendment to achieve success at obtaining a patent.**

**THE TECHNICAL REJECTIONS OF THE CLAIMS HAVE BEEN  
OBVIATED**

All Claims have been rewritten to define the invention more particularly and distinctly so as to overcome the technical rejections and define the invention patentable over the prior art.

## **THE CLAIM OBJECTIONS UNDER 35 USC §112 HAVE BEEN OBVIATED**

Applicant requests reconsideration and withdrawal of the claim objections.

As part of second office action dated June 1, 2004., examiner objected to claims 29, 34, 39, and 41 and rejected them under 35 USC§ 112, first paragraph for noncompliance with written description requirement.

Examiner rejected claims 26-29, 34, and 36-41 under 35 USC§ 112, second paragraph for being indefinite. Explanations for all rejected claims are provided.

Claims 29 and 39 have had the “wafers” and “dog bones” deleted. These claims were originally rejected as being new matter. Applicant believed the discussion of solid composition in the specification included wafers and dog bones, but examiner has explained that the term dog bones, though solid in nature, changed the scope of what was claimed. These claims were rewritten as currently amended claims 29 and 39 to delete wafers and dog bones.

Claims 34 and 41 are currently amended. Examiner stated that the terms “plant derived compounds”, “synthetic orally absorbable nontoxic compounds” and “orally consumed substances that induce weight loss” were not supported by the specification and felt to change the scope of the invention and therefore, be new matter. Applicant believes that these terms are supported by the specification and has copied the exact information found in the specification pages 21-23. The addition of exact plant or synthetic compounds as listed in the specification

has made the claim quite lengthy. Applicant requests constructive assistance to rewrite the claim in a shorter and more general description that is satisfactory to the examiner and the applicant.

Claims 26-29, 34, 36-41 were rejected for being indefinite. Explanations provided for new claims 65-71 that resulted from applicant following examiner's advice to split claim 37 into separate claims.

Claim 26, Examiner noted that the additional ingredient required was not specifically identified. The claim was amended. The indefinite portion is deleted and the claim rewritten to show that the composition could be in the physical form of a liquid, semisolid and solid edible food product.

Claim 27 was indefinite regarding what the fiber was to be soluble in, and examiner questioned the use of the markush group. Applicant has amended 27 to remove the indefinite portion and to remove the markush group.

Claim 28 currently amended. The markush groups were removed to clear the indefinite status.

Claim 29 failed to point out the identity of the additional ingredient. Applicant has amended the claim to show that the composition can exist as a solid or semisolid edible food product as opposed to a liquid beverage.

Claim 30 amended to overcome indefinite status. Claim 30 limits the flavoring agent of claim 24 to a sweetener.

Claim 34 currently amended. Examiner stated that the terms "plant derived compounds", "synthetic orally absorbable nontoxic compounds" and "orally consumed substances that induce weight loss" were not supported by the specification and felt to change the scope of the invention

and therefore, be new matter. Applicant believes that these terms are supported by the specification and has copied the exact information found in the specification pages 21-23. The addition of exact plant or synthetic compounds as listed in the specification has made the claim quite lengthy. Applicant requests constructive assistance to rewrite the claim in a shorter and more general description that is satisfactory to the examiner and the applicant.

Claim 36 was amended. The indefinite status has been overcome. The flavoring agent was narrowed over claim 24 to a sweetener.

Claim 37 currently amended. Applicant appreciates examiner's assistance by phone and recommendation to break this into more than one claim. Applicant has followed examiner's advice. Indefinite phrases have been removed.

Claim 38 currently amended. The markush groups were removed to clear the indefinite status.

Claim 39 currently amended to remove the markush group that the examiner found indefinite.

Claim 40 currently amended to remove the markush group that the examiner found indefinite.

Claim 41 currently amended. Examiner stated that the terms "plant derived compounds", "synthetic orally absorbable nontoxic compounds" and "orally consumed substances that induce weight loss" were not supported by the specification and felt to change the scope of the invention and therefore, be new matter. Applicant believes that these terms are supported by the specification and has copied the exact information found in the specification pages 21-23. The addition of exact plant or synthetic compounds as listed in the specification has made the claim quite lengthy. Applicant requests constructive assistance to rewrite the claim in a shorter and more general description that is satisfactory to the examiner and the applicant.

Claim 64 amended to remove indefinite phrase and to provide greater clarity. This claim has a means clause to show structure and function.

Claim 65 new. Applicant has divided claim 37 as the examiner suggested and claim 65 represents the cardiovascular benefits of the previously submitted claim 37. All terms covered in claim 65 are in the specification. The term “cerebrovascular disease” appears as the synonym “stroke” in the specification.

Claim 66 new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37.

Claim 67 new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37.

Claim 68 new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37.

Claim 69 new dependent claim. Applicant teaches admixing at least one ingredient to invention. Applicant in a similar previous claim used the terms “plant derived compounds”, “synthetic orally absorbable nontoxic compounds”, and “orally consumed substances that induce weight loss” which Examiner felt was indefinite. Applicant believes the previous language was supported by the specification and now has amended the claim to include the various plant derived compounds and synthetically absorbable compounds. Applicant notes that this claim is lengthy and requests Examiner’s constructive assistance with writing the claim to provide the same scope yet reduce the length of the claim.

Claim 70 is new independent claim. Examiner suggested applicant split claim 37 into separate claims. Applicant thanks examiner for his suggestions and has done so. Claim 70 deals with the invention limiting toxin exposure to an animal.

Claim 71 is a new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37.

Claim 72 is a new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37.

Claim 73 is a new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37.

Claim 74 is a new dependent claim. This claim is the same as the dependent claims that follow previously submitted claim 37. Applicant realizes this is a very lengthy claim and requests help in rewriting the claim so that it is acceptable to the patent examiner and still covers what is described on page 20-23 of original specification.

Accordingly applicant submits that the specification does comply with § 112 and therefore requests withdrawal of all rejections.

**THE REJECTION OF CLAIMS 26-29, 34, and 36-41 UNDER SEC. 102 (b) IS OVERCOME.**

**THE CLAIM OBJECTIONS UNDER 35 USC§ 102 ON RINGE HAVE BEEN OBVIATED**

Claims 24-27, 29-31, and 34-36 were rejected as being anticipated by Ringe et al. (US Patent 5,026,689) under 35 USC §102 (b)

Claims 37, and 40-41 were rejected as being anticipated by Ringe et al.(US Patent 5,026,689) under 35 USC §102 (b)

Applicant understands from phone discussions with examiner that applicant's invention as a liquid and semisolid (beverage and pudding are novel over prior art). Applicant notes in office action mailed on 6/01/04 examiner's concern about the solid product portion of applicant's invention as it relates to Ringe (cereal) . Applicant now presents several reasons that applicant's invention is novel and is NOT anticipated by Ringe. If examiner disagrees, then applicant requests constructive assistance to rewrite the claim in an acceptable manner that still includes snack bars as part of applicant's invention. Applicant respectfully requests reconsideration and allowance of these claims for the following reasons.

### **APPLICANT'S INVENTION**

Applicant's invention is orally administered nutritional supplement for ingestion by mammals containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent.

Applicant's novel physical structure including specific fibers with specific physical characteristics and specific biologic functions that allows for applicant's supplement to be delivered in a beverage, semisolid, or solid form. Applicant's specification specifically discusses beverages, powders, puddings, and snack bars.

Applicant's invention is novel in that its physical structure allows a mammal to consume more than 7 grams of fiber per serving in safe, easy, convenient and palatable manner without significant side effects.

Applicant's invention is novel in that its physical structure allows a mammal to consume ultra-high fiber (at least 7 grams per serving) without the need to replace minerals and nutrients that high fiber is known to sequester or block the absorption of.

Applicant's invention is novel in that it provides many new uses. Applicant's invention provides many unique health benefits including dramatic weight loss, and reduction in cardiovascular disease. Applicant's invention also reduces the risk of acquiring or improves certain cancers, heart disease, glucose intolerance, diabetes, metabolic syndrome, hypertension, osteoporosis, constipation, diverticulosis, hemorrhoids, irritable bowel, homocysteinemia, dyslipidemia, hypertriglyceridemia, and high sensitivity C-reactive protein (cardiac inflammation). Applicant's invention can be used to help prevent absorption and speed elimination of ingested toxins.

Applicant's invention is novel in that it provides dramatic weight loss without a mammal having to diet or exercise. Applicant's novel physical structure and composition allows for both an immediate and a long lasting satiety that reduces caloric intake in the meal that follows and reduces or eliminates snacking for several hours.

## Ringe

Ringe (US Patent 5,026,689)

Ringe's invention is a ready-to-eat cereal that is high in soluble fiber and is organoleptically pleasing. Ringe also teaches a method of preparing the cereal and a method of reducing total cholesterol.

Ringe's invention is a complicated composition that has these requirements:

1. Psyllium husk only and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.)
2. Starchy cereal 20-80% of cereal composition. (Column 4 , lines 31-34.)
3. Insoluble fiber is required 5-15% by weight.
4. Soluble/Insoluble fiber ratio of 1 to 5:1
5. Soluble fiber 11%-30% of cereal weight and a minimum of 3 grams per ounce (3-6 grams per ounce) (Column 8 , lines 16-27 .)
6. Salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.)



7. Syrup(Malt or Corn) Malt 1%-8% by dry weight basis (Column 6, lines 54-57 & example1-3).
8. Vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.)
9. Fat content limited to 4% or less. (Column 6 , lines 35-39 .)
10. Fructose restriction to less than about 15%. (Column 6 , lines 20-23.)
11. At least one sweetener (Examples 1-4)
12. Minimum of 15 ingredients (Examples 1-4).
13. Cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

Ringe's invention is directed towards the provision of a high fiber ready-to-eat cereal with superior organoleptic attributes or qualities ...containing a high concentration of soluble fiber. Moreover, in preferred embodiments, the present cereal compositions provide high fiber cereals having soluble fiber predominating. The present invention resides in part **in the particular selection of psyllium as the SOLUBLE fiber source.** (Column 1 , lines 49-58 )

In one method aspect, the present invention provides methods for preparing such novel ready-to-eat cereal products. In another method aspect the present invention resides in methods for reducing people's blood serum cholesterol by a regimen of once daily consumption of the present ready-to-eat cereal. (Column 2, lines 36-41.)

The composition of the ready-to-eat cereal is defined by the weight ratio of soluble to insoluble fiber and maximum fat and fructose levels. The ready-to-eat cereals are further essentially defined by limited concentrations of fructose. (Column 2 , lines 49-52 .)

The ready-to-eat cereal products are further essentially defined by limited concentrations of FRUCTOSE. (Column 2 , lines 54-56 .)

In one method aspect of preparing the ready-to-eat cereal, the methods essentially compromise blending the cereal ingredients with controlled amounts of water, COOKING the mixture to form a cooked cereal, forming the cooked cereal into a cooked cereal dough LOW SHEAR MIXING, and forming the cereal dough into pieces and drying the cereal pieces to form the present ready-to-eat cereals. (Column 2 , lines 60-68 .)

## **APPLICANT'S INVENTION HAS GENERAL DIFFERENCES OVER RINGE**

Applicant's invention is for mammals. Ringe is for humans. (Column 3 , line 3 .)

Applicant's nutritional supplement invention can exist as a liquid (beverage), semisolid (pudding) or solid (snack bar). Ringe exists only in a ready-to-eat **cereal** form, but does provide for various shapes----all shapes strictly related to cereals (i.e., puffed, flake, shreds, biscuits etc). (Column 7-8 , lines 66-68 and 1-6 .) Ringe does teach that different "cereal forms" can be made, but his invention only deals with a ready-to-eat cereal. Ringe does not teach a liquid, pudding, or snack bar.

Overview Differences in structure Ringe vs. Applicant.

**Applicant's invention has different physical structure and omits several element of Ringe yet applicant provides many more health benefits than Ringe. Applicant does not teach elements, ratios, and restrictions that are necessary for Ringe to make a organoleptically pleasing ready-to-eat cereal.**

1. Ringe's invention is dependent on both soluble and insoluble fiber and in a specific ratio of 1 to 5:1 Soluble/Insoluble fiber ratio. The soluble fiber must be 11%-30% of cereal weight and a minimum of 3 grams per ounce. Range of soluble fiber is 3-6 grams per ounce (Column 8 , lines 16-27 .),

**Applicant does not quantify invention on solubility, but rather specific fibers, each with their own physical and biological characteristics.** Applicant does not require insoluble fiber and all examples noted in applicant's specification use only soluble fibers. Therefore, applicant is novel over Ringe as applicant's invention does not need insoluble fiber and does not require soluble/insoluble ratio of 1 to 5:1. Applicant has 7 grams of fiber or more per serving. Ringe does not provide serving size, but rather provides the amount of soluble fiber per ounce. Applicant, a physician notes that Ringe's calculation of 0.8-1.5g/kg of cereal needed per day that can be taken in as little as one serving is unrealistic and would not be tolerated by humans. His calculation becomes even more unreasonable when high levels of psyllium are used. Examiner's example in office action page 9 shows 3 oz of cereal would be necessary for an 80 Kg person. At 7.2 grams of fiber per ounce, and additionally high in psyllium, an individual consuming about 21 grams of fiber would have gastrointestinal problems. Since 2/3 of Americans are overweight the number of grams of fiber Ringe recommends would be much higher than in examiner's example.

Applicant wishes to stress this point. Applicant's novel physical structure and resulting unexpected results, and superior health benefits are tied to the actual types of fibers each having their own physical structure and biological actions. Ringe ties his organoleptically pleasing ready-to-eat cereal to the soluble and insoluble fibers within and the necessity of keeping a soluble/insoluble ratio of 1 to 5:1. Applicant has nothing to do with this solubility issue and feels it is meaningless and inaccurate. Ringe could not have known in an accurate fashion how soluble or insoluble his fibers were. Most of the fibers have both qualities and the method they were prepared could have influenced solubility. Applicant provides the following proof:

***"Because it was presumed that defining the characteristics of fibers by their soluble and insoluble classification could facilitate distinction in biological responses, methods were developed to measure each of these fiber fractions. Improved methods for soluble fiber determination have resulted in increased accuracy regarding content, but it has since become evident that the physiological response to fiber sources based on this measurement is not***

*necessarily predictable on the basis of solubility alone. Other factors, such as fermentability, viscosity, and bile acid binding ability , also contribute to the physiological response to fiber sources. Additionally, since all foods contain a mixture of polysaccharides, only isolated polysaccharides can be simply classified as soluble or insoluble fiber sources. “ (Linda Van Horn, PhD, RD Circulation 1997;95:2701-2704)*

2. Ringe : Psyllium husk only and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.)

Applicant can use any form of psyllium and can use less than 5% by dry weight.

2. Ringe: Starchy cereal 20-80% of cereal composition. (Column 4 , lines 31-34.)

Applicant teaches oat is necessary and oat fiber is preferred. Applicant distinguishes oat fiber by mesh size. Applicant's invention can have less than 20% or more than 80% oat fiber. Ringe does not require oat fiber and does not use it in example 2. When Ringe does use oat, he uses oat bran (examples 1, 3, and 4).

3. Ringe: Insoluble fiber

Applicant's invention does not require insoluble fiber. Ringe teaches the necessity of insoluble fiber and specific ratios that are necessary to keep his ready-to-eat cereal organoleptically pleasing. Applicant omits the need of the insoluble fiber element.

4. Ringe : Soluble/Insoluble fiber ratio of 1 to 5:1

Applicant's novel structure is not based on soluble/insoluble fiber ratios. Applicant's invention can be much higher than a 5:1 ratio. Applicant's invention omits this restriction.

5. Ringe: Soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Col. 8, lines 16-27 .)

Applicant's novel structure is not tied to soluble fiber percentages and can have less than 11% or greater than 30% soluble fiber based on weight.

6. Ringe: Salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.)

Applicant does not teach salt as part of his novel structure.

7. Ringe: Syrup (Malt or Corn) Malt 1%-8% by dry weight basis (Column 6 , lines 54-57 & example 1-3).

Applicant does not teach malt as a necessary component of his novel structure and certainly does not tie the novel structure to a malt content of 1%-8%. Applicant omits a necessary element in Ringe and provides a number of new uses.

8. Ringe: Vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.)

Applicant does not require vitamins as applicant's novel structure does not inhibit absorption of vitamins or minerals. Applicant can add vitamins and as few as one to applicant's invention. Ringe requires a blend of vitamins. Applicant also questions how supplementing vitamins by topically applying them (Column 7, lines 1-3) to a cereal overcomes the insoluble fibers' ability to absorb them. (Just because you add more vitamins, doesn't mean that the insoluble fiber in the cereal won't still prevent absorption of the vitamins and minerals that have been topically applied to the cereal.)

9. Ringe: Fat content limited to 4% or less. (Column 6 , lines 35-39 .)

Applicant's novel structure does not have any fat content restraints. Applicant's invention can contain much more than 4% fat. Applicant's invention can be made without fat. Ringe always contains fat, albeit low fat levels. Applicant omits a necessary element in Ringe and provides a number of new uses.

10. Ringe: Fructose restriction to less than about 15%. (Column 6 , lines 20-23.)

Applicant's invention does not require any fructose, yet teaches no restrictions on fructose. Applicant omits a necessary restriction in Ringe and provides a number of new uses.

11. Ringe: At least one sweetener (Examples 1-4) and teaches a restriction of 0.1% to 30% of composition weight. (Column 5 , lines 64-66 .)

Applicant teaches that a flavoring agent is a necessary component of the novel structure but that flavoring agent can be a non-sweetening flavoring agent. Hence, applicant's invention can be made without a sweetener. When applicant uses a sweetener Sucralose is the preferred sweetening agent. Ringe does not teach sucralose but rather teaches sugar in most examples and also aspartame and potassium acesulfame (Column 8 , lines 6-14 .)

12. Ringe: Minimum of 15 ingredients (Examples 1-4).

Applicant teaches a minimum of 4-5 ingredients are necessary to make the invention.

Applicant omits several necessary elements in Ringe and provides a number of new uses over Ringe.

13. Cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

Applicant does not teach any moisture content and does teach the restriction of 1%-3%.

Applicant omits a necessary restriction in Ringe and provides a number of new uses over Ringe.

14. Ringe teaches a low shearing process is necessary during admixing and cooking. (Column 7, lines 7-11 .) Applicant does not teach a low shearing process and invention can be made without cooking. Applicant omits necessary restrictions in Ringe and provides a number of new uses over Ringe.

15. **Ringe requires a dry base blend requiring a minimum of 8 ingredients (Example 2, a malt syrup blend, and a sweetener.)** Applicant's invention requires only 3 ingredients and a flavoring agent. The fact that applicant's invention omits elements found necessary for Ringe, indicates novelty.

**INDEPENDENT CLAIM 24 RECITES NOVEL PHYSICAL  
FEATURES OVER RINGE UNDER SEC. 102.**

Claim 24 shows applicant's invention is orally administered nutritional supplement for ingestion by mammals containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent. Applicant's nutritional supplement can exist as an edible food product that is liquid, semisolid, or solid. Specifically the semisolid can exist as a pudding. The solid exists as a powder or a snack bar. Each can exist as a zero-calorie food product. The oat, guar, and psyllium all have very specific specifications and physical properties. This novel structure allows for edible food products to be made with very few ingredients and minimal processing. In addition, the novel structure with the physical properties allows for several new uses.

Ringe's invention deals only with a ready-to-eat cereal that is organoleptically pleasing and can exist in different cereal sizes and shapes. Ringe requires a minimum of 15 ingredients to make his cereal and very specific processing to make it. Ringe has numerous ratios and requirements. His complicated invention requires the following :Psyllium (husk only) and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.), starchy cereal 20-80% of cereal composition. (Column 4 , lines 31-34.), insoluble fiber, soluble/Insoluble fiber ratio of 1 to 5:1, soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Column 8 , lines 16-27 .), salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.), syrup (Malt or Corn) malt 1%-8% by dry weight basis (Column 6 , lines 54-57 & exampl-3), vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.), fat content limited to 4% or less. (Column 6 , lines 35-39 .), fructose restriction to less than about 15%. (Column 6 , lines 20-23.), at least one sweetener (Examples 1-4), cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

Additionally, Ringe teaches how the ready-to-eat cereal is made:

Steps (Column 7, lines 17-50)

1. forming a dry blend of cereal components and blending them into a homogenous blend.
2. the homogeneous blend is then combined with controlled amounts of water and **cooked** in a conventional manner in an atmospheric cooker or low pressure extruder cooker.

3. then **cooked with steam** and sufficient amounts of added water for times and temperatures sufficient to gelatinize the cereal starch and develop the desired levels of cooked cereal flavor.
4. The total moisture addition is controlled to provide a cooked cereal comprising about 20% to 60% moisture.
5. The cooked cereal is formed into a dough by an extruder and then extruded in long ropes
6. Then the cereal dough is formed into shapes and sizes desired.

Applicant's invention's ability to provide very high doses of fiber in a unit dose of administration (a serving) without inert carriers, binders, lubricants, syrups, or excipients and provides very important, valuable, and unexpected new results that dramatically improve mammals' (and especially a human's) health. This clearly proves applicant's novel structure is unobvious under Ringe.

Applicant's invention is physically different from Ringe, omits many of Ringe's necessary elements, ratios and restrictions, and does not require Ringe's processing or numerous ingredients. The final edible food product form differs as well. Hence, applicant's invention is novel and clears Ringe over Sec. 102.

**Therefore, applicant submits that it is clear beyond doubt that claim 24 recites novel physical features over Ringe and thus clears Ringe under Sec. 102**

## **APPLICANT ALSO CLEARS RINGE UNDER SEC. 102 AS APPLICANT'S INVENTION HAS NEW USE.**

Applicant's invention with its unique physical structure has a number of new uses not anticipated by Ringe or others.

1. Dramatic weight loss without dieting or exercising



Applicant's invention provides dramatic weight loss without the need to diet or to exercise. The commercial success of the product is proof. No other weight loss invention allows people to eat whatever they want and not exercise.

## 2. Dramatic cholesterol benefits

Applicant's invention provides very dramatic cholesterol benefits. NCEP guidelines state that 10 grams of soluble fiber daily can give a 5% reduction in LDL cholesterol. Applicant's invention has demonstrated up to a 60% reduction in LDL. In addition, applicant's invention has demonstrated up to a 56% increase in HDL and up to an 82% decrease in triglycerides. Applicant provided proof of these claims previously as part of Amendment A. These dramatic benefits could not have been anticipated.

## 3. Dramatic cholesterol benefits in people regardless if a low fat, or low cholesterol diet is followed.

Ringe's invention teaches 5%-20% reductions in total serum cholesterol. This is only if the person has an elevated LDL cholesterol >220mg/dl and only if the individual follows a low fat and low cholesterol diet. Applicant believes Ringe's invention should not be credited at all with a method of reducing cholesterol as the low fat, low cholesterol diet alone could be the sole reason accounting for any reduction. Applicant, a board certified internal medicine physician and expert who teaches other doctors advanced cholesterol evaluation and management also notes that reductions in total cholesterol are not necessary meaningful. Day to day fluctuations could be 30 points or more and total cholesterol is not correlative with heart disease.

Applicant's invention provides dramatic cholesterol benefits well beyond total serum cholesterol and regardless of a person's baseline cholesterol numbers. Applicant's benefits occur without dieting or food restrictions.

## 4. Dramatic cholesterol benefits even for people with normal baseline cholesterol.

Applicant provides dramatic cholesterol benefits irregardless of what your baseline cholesterol numbers are. This is very significant as 50% of Americans die of cardiovascular disease yet

most have total cholesterol's less than 220 mg/dl. These Americans still need cholesterol lowering, despite a total cholesterol of 220mg/dl.

Ringe teaches total cholesterol reduction (not LDL, HDL or triglycerides) only if the baseline cholesterol is greater than 220 mg/dl.

#### 5. Treatment and prevention of metabolic syndrome

Ringe teaches nothing about metabolic syndrome.

Metabolic Syndrome is an extremely common condition in the population and dramatically accelerates the risk of cardiovascular disease. Applicant's novel invention provides a treatment for metabolic syndrome and thereby dramatically decreasing cardiovascular disease.

#### 6. Treatment and prevention of diet-related cancers.

Ringe teaches nothing about diet related cancers.

Applicant's invention gives dramatic weight loss they can help prevent diet-related cancers. Applicant has filed a divisional patent regarding this benefit.

#### 7. Treatment and prevention of glucose intolerance and diabetes.

Ringe: Teaches nothing about glucose intolerance and diabetes.

Applicant's invention improves glucose metabolism and reduces risk of developing insulin resistance, glucose intolerance, and diabetes. Applicant's invention can treat insulin resistance, glucose intolerance, and diabetes. Applicant provided information in specification and Rule 132 Declaration previously.

#### 8. Treatment and prevention of sleep apnea.

Ringe: Teaches nothing about sleep apnea.

Applicant: Teaches that invention can treat or reduce the risk of developing sleep apnea.

#### 9. Treatment and prevention of hemorrhoids, irritable bowel, and diverticulosis.

Ringe: Teaches nothing about diverticulosis, hemorrhoids, or irritable bowel.

Applicant: Teaches invention can treat or reduce the risk of developing diverticulosis, hemorrhoids, or irritable bowel.

10. Treatment and prevention of cardiovascular disease.

Ringe: Teaches nothing about cardiovascular disease.

Applicant: Teaches invention treats or reduces risk of developing cardiovascular disease by multiple mechanisms including lowering LDL cholesterol, raising HDL cholesterol, lowering triglycerides, lowering high sensitivity C-reactive protein, lowering homocysteine, reducing cardiac inflammation, improving glucose metabolism, reducing body weight, and treating metabolic syndrome.

**Applicant's invention is novel as it provides several new uses over Ringe.**

Ringe teaches his invention can reduce PEOPLE'S blood serum cholesterol. (Column 2 , lines 38-41 .) This is limited to a person's total cholesterol- a meaningless number. It is well known that total serum cholesterol values can vary as much as 30 points in a 24 hour period. More importantly total serum cholesterol is a misleading number as it does not give information about the LDL (bad) cholesterol, or the HDL (good) cholesterol. Hence, a high total cholesterol could be advantageous if composed of mostly HDL cholesterol, or it could be dangerous if composed of mostly LDL cholesterol.

Applicant questions whether Ringe's invention lowers total cholesterol at all. Ringe himself states it only works in people with a cholesterol greater than 220 mg/dl, provides at most a 10% reduction, and only if the person is on a low fat, low cholesterol diet for at least 6 weeks. (Column 8 lines 46-50.)

Applicant's invention differs from Ringe's cholesterol reduction in several ways.

Applicant's invention lowers cholesterol regardless of baseline cholesterol. (Ringe needed a low cholesterol, low fat diet to get a 5-20 reduction in total serum cholesterol.

Applicant's invention does not require any low fat or low cholesterol diet.

Applicant's invention is for mammals and not limited to people.

Applicant's invention dramatically improves the individual cholesterol components that make up the total cholesterol number not just total cholesterol.

Applicant's invention provides dramatic weight loss without having to change diet or exercise patterns.

Applicant's invention provides many health benefits including diminishing risk of metabolic syndrome, heart attacks, fat-related cancers, hemorrhoids, diverticulosis, irritable bowel, diabetes, glucose intolerance, insulin resistance, hypertension, osteoporosis, sleep apnea colon cancer .

Applicant has provided examiner with proof of dramatic cholesterol improvement with individuals who have taken applicant's invention. Applicant has demonstrated up to a 60% drop in LDL, up to an 82% drop in triglycerides, and up to a 56% elevation in HDL cholesterol. In addition, applicant has provided proof of lowering high sensitivity C-reactive protein.

**Therefore, applicant submits that it is clear beyond doubt that applicant's invention is novel and provides several new uses over Ringe and thus clears Ringe under Sec. 102**

## **THE NOVEL PHYSICAL FEATURES OF CLAIM 24 ARE UNOBVIOUS OVER RINGE UNDER SECTION 103**

Applicant submits that the above novel physical features of claim 24- including the ultra-high fiber (at least 7 grams per serving) composition comprising three specific fibers guar, oat, and psyllium each with specific physical characteristics and biological properties and the addition of at least one flavoring agent is unobvious over Ringe for a variety of reasons listed below.

**Applicant's invention could not have been anticipated by Ringe, as applicant does not follow Ringe's teachings, elements, ratios, or percentages that are required to make a high fiber supplement that is organoleptically pleasing.** Applicant notes it is not obvious that a organoleptically pleasing high fiber supplement could be made ignoring what Ringe considers essential elements, ratios, and percentages-all key to his invention.

Applicant notes that Ringe teaches a ready-to-eat cereal composition, method of making this ready-to-eat cereal, and a method of total serum cholesterol reduction.

Applicant teaches a novel nutritional composition that can exist as a solid, semisolid or liquid food product. Specifically, applicant teaches a liquid, powder, pudding and snack bar.

Ringe does teach different sizes and shapes of ready-to-eat cereal are possible such as flakes, puffed cereals, shreds, biscuits, and toasted flakes. (Column 6 , lines 1-5 .) Ringe does not teach a liquid, powder, pudding, or snack bar. In addition Ringe teaches a minimum of 15 ingredients are needed to make his invention and special processing such as low shear mixing, and cooking are required. Applicant can make food products in as few as 4-5 ingredients and they do require any special processing.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBLIVIOUS AS IT PRODUCES UNEXPECTED RESULTS.**

Applicant's invention has novel physical structure of an ultra-high fiber (at least 7 grams per serving) composition comprising three specific fibers guar, oat, and psyllium each with specific physical and biological characteristics and the addition of at least one flavoring agent is unobvious over Ringe for a variety of new and unexpected reasons listed below.

Applicant, a board certified internal medicine doctor and expert in advanced lipid treatment has noted several unexpected results amongst patients and users of his invention.

- (a) Safe, fast, easy weight loss occurs even in individuals who claim they have failed all diets. It is unexpected to see weight loss in individuals who have failed all other diets. Applicant has witnessed steady weight loss in his patients, and has received numerous comments regarding successful weight loss in individuals who have stated they failed all previous diets. Many individuals have successfully kept the weight off for more than 2 years without regaining weight thus avoid yo yo dieting common amongst all diet plans. It is unexpected to have a diet product allow consistent weight loss without regaining weight.

Applicant's invention's extremely high reorder rate is further proof of successful weight loss. Applicant's invention works better than other weight loss products and is safer because it does not contain dangerous stimulants. The avoidance of yo yo dieting is also a safety factor as yo yo dieting has been recently found to cause a variety of health issues, including damaging an individual's immune system. **Ringe's invention is not a weight reduction formula.** Ringe does not teach weight loss. He offers no method, means or proof his invention can be used for weight loss. Applicant's invention produces safe and effective weight loss and is seen as an unexpected valuable benefit over Ringe's invention.

- (b) Weight loss occurs without need for food restriction and exercise. All diets not using orally consumed stimulants combine food restriction and/or exercise as a necessary part of the diet. Applicant's invention promotes satiety that is long lasting and curbs appetite so that less food is consumed despite individuals eating their "normal" diet. Applicant believes novel physical structure and biological properties allows weight loss to occur by other mechanisms described in specification as well. Applicant believes these special fibers have a biological synergism that produces the numerous unexpected results. Applicant's invention works much better than other weight loss products because the need for will power to restrict certain foods is unnecessary, and the individual does not

have to exercise. Applicant's invention is specifically designed to maximize health benefits of fiber especially weight loss.

(c) Dramatic reduction in the risk of heart disease due to one or more factors including reversal of metabolic syndrome, weight loss, improvement in cholesterol, triglycerides, lipids, high sensitivity C-reactive protein and homocysteine. Applicant, a physician, has documented marked reduction in risk of cardiovascular disease in numerous patients, and non-patient users who have communicated with applicant. This information has been documented and submitted previously as a Rule 132 Declaration. Applicant has documented reversal of metabolic syndrome, spectacular weight loss, and improvement in all lipid parameters as well as non-lipid cardiac risk factors homocysteine and high sensitivity C-reactive protein. Applicant has documented new and unexpected results in improvement of lipid parameters. American doctors are taught to observe national guidelines for treatment of lipid disorders. These guidelines are based on the National Cholesterol Education Program Adult Treatment Program III guidelines (NCEP ATP III 2001 V 20-21) . NCEP ATP III teaches that 5-10 grams of soluble fiber only can lower LDL by 5% (NCEP ATP III V20-21). **Applicant has documented LDL cholesterol drops of over 100 points and reductions of up to 60%. It is unexpected to achieve a 60% reduction in LDL cholesterol when national guidelines teach only 5% reduction.** (Ringe teaches 5%-20% reduction but it is not in LDL cholesterol, but rather the near-meaningless total cholesterol number. Ringe cannot even demonstrate his Applicant's invention alone, can make this reduction, as he requires a low fat, low cholesterol diet) .

Additionally, applicant has documented **triglyceride reductions of up to 82%**. This is totally unexpected and provides reductions as good as or better than top prescription medications. Ringe does not teach triglyceride reduction.

HDL cholesterol, the good cholesterol, serves as a reverse cholesterol transport. The higher the HDL level, the lower the risk of heart disease. Each one point increase in HDL correlates with a 3-4% reduction in heart disease. Applicant has documented **HDL rises** as high as **22 points and elevations as high as 56% over baseline**, this is **unexpected** as the NECP ATP III guidelines (V-20) show that soluble fiber **reduces** HDL. "Some investigators report that the consumption of viscous (soluble) fiber (provided by oats, barley, psyllium, pectin-rich fruit, and beans ) produces a **reduction** in HDL cholesterol concentration (Anderson 1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a). Ringe teaches no HDL cholesterol elevation.

Applicant's unexpected dramatic cholesterol improvements have resulted in numerous patients reducing their cholesterol medication, or eliminating the need for them altogether. In the most dramatic cases, patients have eliminated the need for 3 cholesterol medications that were at maximum doses! Ringe does not teach his composition can reduce or eliminate the need for cholesterol medications. Ringe does not teach his invention can lower LDL cholesterol and triglycerides, or raise HDL cholesterol. Ringe only teaches a mild lowering of total serum cholesterol can occur in humans with total cholesterol values greater than 220mg/dl and ONLY if they follow a low fat and low cholesterol diet. Applicant's invention provides dramatic benefits in ALL cholesterol parameters and without regard to baseline cholesterol or a low fat, low cholesterol diet. Applicant produces new and unexpected results over Ringe.

Applicant has documented dramatic improvement in reducing cardiac inflammation as judged by high sensitivity C- reactive protein levels. Applicant's formula has taken people in the two highest quintiles of inflammation and reduced them to the lowest quintile of inflammation. This correlates with a quintile 4-5 improved to a quintile 1; greatly reducing the risk reduction in cardiovascular disease. Ringe does not teach



improvement or even mention high sensitivity C-reactive protein. Applicant produces new and very valuable unexpected results over Ringe.

**Applicant wishes to respectfully point out that Ringe's invention as a method of reduction of total serum cholesterol is meaningless. Total cholesterol has very little correlation with heart disease and that is why doctors should not use it in decision making.** Total serum cholesterol can vary as much as 30- points in a 24 hour period, also making it an unreliable measurement tool when trying to compare 2 or more values. Ringe provides no method, means, or proof his actual composition would result in any lipid parameter improvement (beyond the total serum cholesterol reduction). Applicant's invention provides panlipid parameter improvement and this could not have been anticipated by Ringe as Ringe only provided for a method of total serum cholesterol reduction ( near-meaningless reduction in cardiovascular disease) if a low fat and low cholesterol diet is followed. One would not even have faith that Ringe could lower anything as the low fat, low cholesterol diets are generally accepted to lower total cholesterol. Furthermore, it is totally unexpected when national guidelines and research quote soluble fiber can reduce LDL by 5% to get up to 60% reductions. Furthermore, no researcher could have anticipated applicant's invention could reduce the need for cholesterol medications or eliminate the need all together, especially when an individual required maximum dose of 3 cholesterol medications.

**Ringe does not teach improvement in HDL. It is totally unexpected when national guidelines and research quote soluble fiber reduces HDL to get up to a 56% improvement.** Applicant produces new and unexpected HDL results over Ringe..

Ringe does not teach improvement in high sensitivity C-reactive protein. Applicant is unaware of research showing fiber lowers high sensitivity C-reactive protein yet applicant's invention has improved high sensitivity C-reactive protein in many individuals taking the invention, and some have received maximal improvement.

Applicant produces new and unexpected results in high sensitivity C-reactive protein and resulting cardiac inflammation over Ringe.

(d) Another new and unexpected result of applicant's invention is that vitamin and mineral supplementation is not needed. High fiber food products need to be supplemented with vitamins and minerals because the fiber blocks their absorption. This information can be found in virtually all patents that claim to have a substantial amount of fiber. Applicant's invention does not require any supplementation of vitamins or minerals.

Ringe teaches that a vitamin blend is needed with his invention in order to make up for vitamins and minerals lost through consumption of his invention. Each of his examples includes a **vitamin blend**. Applicant respectfully does not understand how Ringe's coating vitamins on his invention solves the absorption problem. Why would coating vitamins on top of insoluble fiber allow absorption of the vitamins, when insoluble fiber by its nature blocks absorption of some vitamins and minerals. Applicant respectfully feels Ringe vitamin blend is nothing more than a theoretical benefit based on poor logic. Ringe offers no proof that the vitamin blend works. **Applicant believes Ringe's invention would likely require vitamins and minerals to be consumed at some time daily independent of when the cereal is consumed.** It is a new and unexpected valuable benefit that applicant's novel physical structure provides for consumption of an ultra high fiber (7 grams or more per serving) supplement without the need for supplemental minerals or nutrients.

(e) Still another unexpected new use of applicant's invention is that it can be used to help prevent or treat metabolic syndrome. This is an important contribution to any mammals' health as metabolic syndrome dramatically accelerates cardiovascular disease. No prior art shows that fiber can treat or prevent metabolic syndrome.

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Ringe. These include safe, and easy weight loss, the ability to lose weight without dieting or exercise, the ability to avoid yo yo dieting, the treatment or prevention of metabolic syndrome, the dramatic reduction in risk of cardiovascular disease, the panlipid improvement in cholesterol, lipids, and triglycerides, the reduction of cardiac inflammation and high sensitivity C-reactive protein, and the ability to consume large amounts of fiber over time without the need for vitamin and mineral supplementation. This clearly proves that applicant's novel structure is unobvious over Ringe and clears Ringe under Sec. 103.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED UNWORKABILITY.**

It is unobvious that more 7 or more grams of fiber could be delivered without vitamin and mineral supplementation. As noted above, it is well known in the art that substantial fiber consumption leads to vitamin and mineral deficiencies that require supplementation. Ringe teaches insoluble fiber prevents vitamin and mineral absorption. (Column 6, lines 58-68.) This is why he includes a "vitamin blend" in all his examples. Applicant's invention has novel physical structure comprising guar, oat, and psyllium with specific physical characteristics, at least one flavoring agent, and administered in a minimum of 7 gram of fiber per serving dosage. Applicant overcomes the assumed unworkability by allowing an individual to safely consume 7 or more grams per serving one or more times daily and without the need for nutrient supplementation. Applicant notes **in over two year's worth of use, there have been no safety issues, no need to supplement minerals or nutrients, and users have had no serious side effects. Some of these individuals have consumed more than 34 grams of applicant's novel fiber supplement daily!**

Applicant's invention's ability to safely deliver a minimum of 7 grams of fiber per serving to a mammal without the need for nutrient supplementation clearly proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED INSOLUBILITY.**

Up to present, those skilled in the art have avoided high doses of fiber due to side effects, and concern about high fiber being dangerous through interfering with absorption of nutrients (Ringe column 1 58-63).

Applicant, a board certified internal medicine physician, has communicated with numerous patients and buyers of his invention who take more than 17 grams of fiber per day (some more than 34 grams per day), without significant side effects or any evidence of nutrient or mineral deficiency. It is well known in the art that large amounts of fiber cause gastrointestinal symptoms. This is why most fiber containing products limit the fiber per serving to a maximum of 2-3 grams per serving. In addition, up to now, Ringe and others skilled in the art felt high dose fiber necessitated mineral and nutrient supplementation. Applicant's invention has solved both of these problems by allowing delivery of ultra high fiber (7 or more grams of fiber per serving) at one serving, and more than 34 grams per day without gastrointestinal problems or the necessity for nutrient and mineral supplementation.

Applicant's invention's ability to deliver higher doses of dietary fiber more than 34 grams per day safely and without danger, risk, or need for vitamin or mineral supplementation proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

Another insolubility issue applicant solves is the ability to reduce panlipid parameters in mammal. Ringe teaches that his invention reduces total serum cholesterol 5%-20%. In order to get these mild gains the human must have a total serum cholesterol above 220mg/dl and must follow a low cholesterol, low fat diet. Nowhere in Ringe's patent does he teach his invention will work without a low fat, low cholesterol diet. Ringe provides no method, means, or proof

that his composition improves the significant lipid parameters (LDL cholesterol, HDL cholesterol, and triglycerides). Applicant has solved the problem on how to reduce cardiovascular risk by providing panlipid improvement in a mammal.

Applicant teaches how fiber can be used to provide dramatic weight loss without dieting or exercise and without the dangers of yo yo dieting. Ringe does not teach weight loss. Applicant provides weight loss and significant lipid parameter benefits showing his novel structure has overcome unworkability.

Applicant's invention with novel physical structure allows delivery of at least 7 grams of fiber per serving, safely, without risk or danger to the user, and without the need for vitamin supplementation. Applicant also provides dramatic weight loss and cardiovascular risk reduction/ cholesterol benefits for the user. Applicant provides a solution to obesity, dyslipidemia, the gastrointestinal side effects of fiber, the necessity for vitamin and mineral supplementation and the dangers of high fiber consumption proving that applicant's novel structure solves many previously unresolved problems and is unobvious over Ringe under Sec. 103.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO OMISSION OF ELEMENT(S)**

Ringe's invention requires a minimum of 15 ingredients to make his invention. His complicated invention requires the following: Psyllium (husk only) and makes up 5%-37% of the cereal weight (Column 4, lines 4-19.), starchy cereal 20-80% of cereal composition. (Column 4, lines 31-34.), insoluble fiber, soluble/Insoluble fiber ratio of 1 to 5:1, soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Column 8, lines 16-27.), salt 0.1-2% (Column 6, lines 51-54 and additionally in all 4 examples.), syrup (Malt or Corn) malt 1%-8% by dry weight basis (Column 6, lines 54-57 & exampl-3), vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6, lines 58-68.), fat content limited to 4% or

less. (Column 6 , lines 35-39 .), fructose restriction to less than about 15%. (Column 6 , lines 20-23.), at least one sweetener (Examples 1-4), cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

Applicant's invention omits many elements. Applicant does not require ratios, percentages, and restrictions of Ringe. Applicant does not need insoluble fiber nor a specific ratio of soluble to insoluble fiber . Applicant's invention can be made with a minimum of 4 or 5 ingredients. Ringe requires special processing including low shear mixing and cooking. Applicant does not require special processing. Whereas Ringe teaches a complicated formula , applicant teaches a much simpler formula that omits many elements of Ringe. Despite omitting so many elements of Ringe, applicant provides new and very important benefits over Ringe.

Applicant's omission of several of Ringe's elements and provides several new and valuable uses proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS A COMMERCIAL SUCCESS.**

Previously submitted Declaration under Rule 132. Applicant has successfully been selling invention by word of mouth for more than 2 years. Re-buy rates are extremely high showing satisfaction with the product. Applicant has been approached by a well-known cardiologist to make him a product he can private label. Applicant has been approached by various business people who want to help market the invention.

### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS IN A CROWDED ART**

The benefits of fiber are well accepted. Fiber supplements and weight loss supplements are a crowded field, therefore any step forward however small should be regarded as significant. Ringe does not provide information that **his** fiber composition improves LDL cholesterol, HDL

cholesterol. Triglycerides, high sensitivity C reactive protein or reduces weight. He does not provide a method, means, or specific information that his composition offers any benefit of weight reduction or cholesterol improvement (other than the total cholesterol reduction when accompanied by a low fat, low cholesterol diet.) Even the best fiber regimen that researchers could postulate only offered a 5% reduction of LDL cholesterol (NCEP ATP III 2001 V20-21).

Applicant's invention as listed in claim 24 provides several steps forward over Ringe. Applicant's invention provides dramatic weight loss and cardiovascular risk reduction, as well as dramatic improvement in cholesterol, lipids, triglycerides, high sensitivity C-reactive protein, homocysteine, glucose metabolism, digestive diseases, and metabolic syndrome and provides a number of other health benefits. Applicant's invention provides weight loss without dieting or exercise, and allows consumption of more than 34 grams of fiber per day without the need to supplement minerals and vitamins. These are all large improvements over Ringe and others.

Applicant's invention's numerous health benefits provided over Ringe's fiber composition proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND OFFERS AN UNAPPRECIATED ADVANTAGE.**

Applicant's invention according to claim 24 offers several unappreciated advantages. Ringe teaches that "fiber, especially insoluble fiber, is believed to affect adversely selected mineral and vitamin absorption." (Column 6 , lines 58-59.) Ringe therefore puts a "vitamin blend" into each of his examples.

Applicant's invention does not require vitamin or mineral supplementation. This offers a huge advantage as one does not need to worry that certain vitamins or minerals are being depleted and ultimately endangering the individual's health. In more than 2 years of selling his invention, applicant notes no vitamin, or mineral deficiencies or any health problems even when more than 34 grams of fiber of applicant's invention were taken daily.

Applicant's invention provides an ultra-high fiber (at least 7 grams per serving) supplement with very specific fibers each having important physical and biological characteristics. This novel structure, provides many unappreciated advantages. One of which is the fact that vitamins and minerals are not required in the composition. Ringe and others skilled in the art, could not have anticipated the dramatic weight loss, lipid benefits and other health advantages such as lowering of high sensitivity C-reactive protein. NCEP ATP III guidelines teach that soluble fiber at 5-10 grams per day provides only a 5 % reduction in LDL cholesterol. These guidelines also teach that HDL is usually lowered. Applicant's invention has lowered LDL by as much as 60% and typically raises the HDL. In a particularly dramatic case the HDL was raised 22 points (a 56% elevation). (Each HDL point increase is equivalent to a 3-4% risk reduction in cardiovascular disease). These dramatic benefits could not have been anticipated.

Applicant's invention's numerous unappreciated advantages provided over Ringe's fiber composition proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND HAS NOT BEEN IMPLEMENTED.**

Applicant's invention is novel and unobvious. If the invention were obvious, if the advantages were obvious, Ringe and those skilled in the art would have surely developed it by now. The fact that Ringe and those skilled in the art have never created applicant's invention indicates it is not obvious.

The fact that applicant's invention was not previously created proves that applicant's novel structure is unobvious over Ringe under Sec. 103.



**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND QUOTED  
REFERENCE IS MISUNDERSTOOD.**

Applicant believes all claims show that invention is unobvious and that Ringe as a reference does not apply to applicant's invention.

Ringe's invention only deals with a ready-to-eat cereal that can come in different cereal sizes and shapes (shreds, biscuits, flakes, puffs). (Column 7, lines 65-68 .) (Column 8 , lines 1-5 .)

Applicant's invention can exist as a liquid, semisolid or solid food product. The novel physical structure with omission of Ringe's elements, ranges, percentages and ratios shows this is a novel and unobvious invention. Applicant offers numerous new and unanticipated uses over Ringe and others.

Applicant respectfully feels that Ringe as a reference was misunderstood in respect to applicant's invention. Applicant believes that all claims prove the applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS CONTRARIAN  
INVENTION OVER PRIOR ART**

Ringe teaches to make a ready-to-eat cereal that requires a minimum of 15 different ingredients. Ringe teaches the importance of specific ratios for psyllium, starchy cereal, and soluble to insoluble fiber. Ringe teaches oat fiber is not required. Ringe teaches that vitamin and mineral supplementation are necessary.

Applicant teaches that an ultra-high dose fiber at least 7 grams of fiber per serving can be made with as few as 4 or 5 ingredients and can be made into an edible food product that is well tolerated. Applicant teaches a liquid and semisolid food product in addition to a solid one.

Applicant teaches that oat fiber is a necessity to this composition. Applicant teaches his invention does not require vitamin or mineral supplementation.

Applicant's invention is contrarian to what Ringe teaches and therefore proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND BELIEVES RINGE IS A "PAPER PATENT".**

Applicant is a board certified internal medicine physician who has made other nutritional supplements and skin care products. Applicant is aware of most treatments for improving health and preventing disease, whether prescription, over the counter, or through a variety of marketing channels. Applicant is unaware of Ringe's invention in the market place and he believes it is not currently being made or sold and is in fact a 'paper patent'. Applicant believes Ringe's invention was never implemented or commercialized and therefore should be construed narrowly. As stated in office action page 9 first paragraph, Ringe fiber content is 7.2-7.7 grams per ounce and he teaches that an 80 kg. person would need about 3 ounces. Ringe teaches it can be eaten 1-3 times daily. In this example 22-23 grams of fiber could be consumed in one sitting. Applicant notes that this much fiber in one setting is usually tied to gastrointestinal complaints, bloating, cramping, and diarrhea. Even more disturbing is that Ringe teaches "high" psyllium content, which is particularly prone to gastrointestinal bloating, cramping and diarrhea. Applicant based above example on the one examiner provided. Since most Americans weigh over 80 Kg and some more than twice that weight, Ringe's recommendations for consuming his invention do not seem reasonable. Applicant cannot imagine a 250 lb (113 kg) individual consuming nearly 30 grams of fiber high in psyllium in one sitting. Applicant respectfully notes that Ringe does not teach how his product is tolerated and the dangers of consuming that much fiber at one time. Applicant believes Ringe's invention was never made.

To the contrary, applicant's invention is sold commercially and is commercially successful.

Applicant believes Ringe's invention is a paper patent where as applicant's invention is commercially successful. Therefore, Ringe's invention should be construed narrowly and this proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND NO CONVINCING REASONING IS PROVIDED.**

Applicant's supplement as listed in claim 24 is novel and unobvious and that is why it was never made before. Ringe teaches a minimum of 15 ingredients are needed, whereas, applicant notes that the edible food product can be made with 4 or 5 ingredients. Ringe's complicated ratio driven composition would not anticipate applicant's simpler to make composition, nor the added health benefits of applicant's invention.

Applicant believes claim 24 further shows that invention is unobvious and that Ringe as a reference does not apply to applicant's invention and that no convincing reasoning exists as to the obviousness of applicant's invention.

Applicant respectfully does not see a convincing line of reasoning as to why the claimed subject matter as a whole, including the multiple differences noted over the prior art, would have been obvious thus proving that applicant's novel structure is unobvious over Ringe under Sec. 103.

**INDEPENDENT METHOD CLAIM 37 RECITES NOVEL  
PHYSICAL FEATURES OVER RINGE AND CLEARS RINGE  
UNDER SEC. 102**

Claim 37 was rejected under 35 U.S.C 102(b) as being unpatentable as being anticipated by Ringe et al. (US patent 5,026,689).

Claim 37 has been amended. Examiner suggested the previous claim 37 be split into different claims. Applicant has complied. Applicant believes claim 37 clears Ringe under section 102 due to novel physical structure that omits several elements of Ringe, and new use in that applicant's method is different.

Claim 37 states:

A method of improving the health of a mammal comprising orally administering a nutritional supplement containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent to a mammal at least one time daily whereby consumption results in at least one health benefit achieved by treating at least one medical condition selected from the group of medical conditions consisting of overweight, obesity, fiber deficiency, poor nutrition, insulin resistance, glucose intolerance, diabetes, hypertension, metabolic syndrome, cardiovascular disease, osteoporosis, sleep apnea, constipation, diverticulosis, hemorrhoids, irritable bowel syndrome, and diet-related cancers.

### **THE CLAIM OBJECTIONS UNDER 35 USC§102 ON RINGE HAVE BEEN OBVIATED**

Claims 37, 40-41 were rejected as being anticipated by Ringe (US Patent 5,026,689) under 35 USC §102

Applicant understands from phone discussions with Examiner that Applicant's invention as a liquid and semisolid (beverage and pudding are novel over prior art). Applicant notes in office action mailed on 6/01/04 examiner's concern about the solid product portion of applicant's invention (snack bar) as it relates to Ringe (cereal). Applicant now presents several reasons that applicant's invention is novel and is NOT anticipated by Ringe. If examiner disagrees, then applicant requests constructive assistance in order to include snack bars as part of applicant's

invention. Applicant respectfully requests reconsideration and allowance of these claims for the following reasons.

**Applicant wishes to save examiner time in reading this amendment. Applicant will raise arguments previously raised above but will keep the detailed explanations to a minimum. If examiner wishes more detail then applicant respectfully asks examiner to review responses above for how claim 24 cleared Ringe over Sec. 102 and 103.**

### **APPLICANT'S INVENTION**

Applicant's invention is orally administered nutritional supplement for ingestion by mammals containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent.

Applicant's novel physical structure including specific fibers with specific physical characteristics and specific biological functions allows for applicant's supplement to be delivered in a beverage, semisolid, or solid form.

Applicant's invention is novel in that its physical structure allows a mammal to consume more than 7 grams of fiber per serving in safe, easy, convenient and palatable manner without significant side effects. Novel physical structure allows a edible food product to be made with a minimum of 4-5 ingredients.

Applicant's invention is novel in that its physical structure allows a mammal to consume ultra-high fiber (at least 7 grams per serving) without the need to replace minerals and nutrients that high fiber is known to sequester or block the absorption of.

Applicant's invention is novel in that it provides many new uses. Applicant's invention provides many unique health benefits including dramatic weight loss, and reduction in

cardiovascular disease. Applicant's invention also reduces the risk of acquiring or improves certain cancers, heart disease, glucose intolerance, diabetes, metabolic syndrome, hypertension, osteoporosis, constipation, diverticulosis, hemorrhoids, irritable bowel, homocysteinemia, dyslipidemia, hypertriglyceridemia, and high sensitivity C-reactive protein (cardiac inflammation). Applicant's invention can be used to help prevent absorption and speed elimination of ingested toxins.

Applicant's invention is novel in that it provides dramatic weight loss without a mammal having to diet or exercise. Applicant's novel physical structure and composition allows for both an immediate and a long lasting satiety that reduces caloric intake in the meal that follows and reduces or eliminates snacking for several hours.

## **Ringe**

Ringe (US Patent 5,026,689)

Ringe's invention is a ready-to-eat cereal that is high in soluble fiber and is organoleptically pleasing. Ringe also teaches a method of preparing the cereal and a method of reducing total cholesterol.

Ringe's invention is a complicated composition that requires:

1. Psyllium husk only and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.)
2. Starchy cereal 20-80% of cereal composition. (Column 4 , lines 31-34.)
3. Insoluble fiber
4. Soluble/Insoluble fiber ratio of 1 to 5:1
5. Soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Column 8 , lines 16-27 .)
6. Salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.)
7. Syrup (Malt or Corn) Malt 1%-8% by dry weight basis (Column 6 , lines 54-57 & examp1-3).
8. Vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.)

9. Fat content limited to 4% or less. (Column 6 , lines 35-39 .)
10. Fructose restriction to less than about 15%. (Column 6 , lines 20-23.)
11. At least one sweetener (Examples 1-4)
12. Minimum of 15 ingredients (Examples 1-4).
13. Cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

In one method aspect, the present invention provides methods for preparing such novel ready-to-eat cereal products. In another method aspect the present invention resides in methods for reducing people's blood serum cholesterol by a regimen of once daily consumption of the present ready-to-eat cereal. (Column 2 , lines 36-41. )

"The present invention provides cereal compositions and ready-to-eat cereals fabricated therefrom as well as to methods for preparing such ready-to-eat cereals. The cereal compositions essentially comprise psyllium husk, a starchy cereal component, and an insoluble fiber source. The cereal contains at least 3 g/oz of soluble fiber. The composition of the ready-to-eat cereal is defined by the weight ratio of soluble to insoluble fiber and maximum fat and fructose levels. The ready-to-eat cereals are further essentially defined by limited concentrations of fructose." (Column 2 , lines 41-52 .)

## **APPLICANT'S INVENTION HAS GENERAL DIFFERENCES OVER RINGE**

Applicant's invention is for mammals. Ringe is for humans. (Column 3 , line 3 .)

Applicant's nutritional supplement invention can exist as a liquid (beverage), semisolid (pudding) or solid (snack bar). Ringe exists only in a ready-to-eat **cereal** form, but does provide for various shapes----all shapes strictly related to cereals (i.e., puffed, flake, shreds, biscuits etc). (Column 7-8 , lines 66-68 and 1-6 .) Ringe does teach that different "cereal forms" can be made, but his invention only deals with a ready-to-eat cereal. Ringe does not teach a liquid, pudding, or snack bar.

Overview Differences in structure Ringe vs. Applicant.

In brief, Applicant can make nutritional supplement with as few as 4-5 ingredients that can exist as a zero calorie liquid, semisolid or solid. The 3 specific fibers offer novelty with specific physical characteristics and biologic function. Ringe is only a ready-to-eat cereal that has numerous elements, ranges, ratios and percentages not required by applicant. Especially important is Ringe requires insoluble fiber, applicant does not.

For more thorough explanation Applicant directs examiner to pages 23-38.

**Therefore, applicant submits that it is clear beyond doubt that claim**

**37 recites novel physical features over Ringe and thus clears Ringe under Sec. 102**

**Applicant also clears Ringe under Sec. 102 as applicant's invention has new uses.**

One test of novelty is new use. Applicant's invention has numerous new uses. Whereas, Ringe teaches **ONLY total serum cholesterol lowering in a person with total cholesterol of 220mg/dl or greater and only if that person follows a low fat, low cholesterol diet**, Applicant teaches a number of new uses that could not have been anticipated by Ringe and provide very valuable health benefits to a mammal. Applicant teaches dramatic LDL cholesterol and triglyceride reduction and HDL cholesterol elevation (This is very different than teaching reduced total cholesterol, a near meaningless number). Applicant teaches dramatic weight loss without the need to diet or exercise. Applicant teaches that his invention can reduce the risk of developing or assist in treatment of medical conditions including overweight, obesity, insulin resistance, glucose intolerance, diabetes, hypertension, metabolic syndrome, cardiovascular disease, osteoporosis, sleep apnea, constipation, diverticulosis, hemorrhoids, irritable bowel syndrome, and diet-related cancers.



**Applicant's physical structure is totally different than Ringe and therefore novel over Ringe.** Applicant's supplement comprises 3 specific fibers with specific physical characteristics (guar, oat, and psyllium) in addition to a flavoring agent. Ringe requires Psyllium (husk only) and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.), starchy cereal 20-80% of cereal composition. (Column 4 , lines 31-34.), insoluble fiber, soluble/Insoluble fiber ratio of 1 to 5:1, soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Column 8 , lines 16-27 .), salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.), syrup (Malt or Corn) malt 1%-8% by dry weight basis (Column 6 , lines 54-57 & examp1-3), vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.), fat content limited to 4% or less. (Column 6 , lines 35-39 .), fructose restriction to less than about 15%. (Column 6 , lines 20-23.), at least one sweetener (Examples 1-4), cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

Applicant's invention omits many of Ringe's necessary ingredients, ratios and percentages.

Applicant does not require insoluble fiber or the soluble fiber to insoluble fiber ratio of 1 to 5:1. Therefore, applicant's invention has novel physical structure over Ringe.

Ringe provides a method for making his ready-to-eat cereal and a separate method to lower total serum cholesterol.

Applicant has different methods. Applicant teaches the invention can exist as a liquid, semisolid, or solid and contain zero calories. Applicant teaches semisolid and solid food products specifically a pudding and a snack bar. Applicant teaches multiple health benefits including dramatic weight loss, and reduction in cardiovascular disease. Applicant's invention also provides many new uses and reduces the risk of acquiring or improves certain cancers, heart disease, glucose intolerance, diabetes, metabolic syndrome, hypertension, osteoporosis, constipation, diverticulosis, hemorrhoids, irritable bowel, homocysteinemia, dyslipidemia, hypertriglyceridemia, and high sensitivity C-reactive protein (cardiac inflammation).

Applicant's invention can be used to help prevent absorption and speed elimination of ingested toxins.

Ringe teaches only one health benefit and that is the reduction of total serum cholesterol.

Applicant respectfully questions whether Ringe provides the reduction of total serum cholesterol as Ringe requires a low fat, and low cholesterol diet to accompany his invention. It is common knowledge that eating a low fat, low cholesterol diet can lower total serum cholesterol so how does one know if Ringe's invention adds any reduction at all?

Applicant teaches several new uses that provide very valuable health benefits as described above and has sent proof in the form of a Rule 132 Declaration. Therefore, claim 37 showing applicant's novel structure clears Ringe over Sec. 102.

### **INDEPENDENT METHOD CLAIM 37 SHOWS NOVEL PHYSICAL STRUCTURE THAT IS UNOBVIOUS OVER RINGE AND CLEARS RINGE UNDER SEC. 103**

Claim 37 was rejected under 35 U.S.C 102(b) as being unpatentable as being anticipated by Ringe et al. (US patent 5,026,689)

Applicant submits that the above novel physical features of claim 37 are unobvious over Ringe under Sec. 103 because applicant's invention produces multiple new and unexpected results. Applicant teaches multiple health benefits including dramatic weight loss, and reduction in cardiovascular disease. Applicant's invention also reduces the risk of acquiring or improves certain cancers, heart disease, glucose intolerance, diabetes, metabolic syndrome, hypertension, osteoporosis, constipation, diverticulosis, hemorrhoids, irritable bowel, homocysteinemia, dyslipidemia, hypertriglyceridemia, and high sensitivity C-reactive protein (cardiac

inflammation). Applicant's invention can be used to help prevent absorption and speed elimination of ingested toxins.

Applicant submits that the above novel physical features of claim 37 comprising guar, oat and psyllium each with specific physical characteristics and biological functions, and at least one flavoring agent produces new and unexpected results over Ringe. The applicant's invention has created numerous new and unexpected results listed above and including dramatic weight loss without the need to diet.

These health benefits could not have been anticipated based on Ringe. Certainly, Ringe would have taught weight loss had he felt it was possible with his invention. Applicant's unique physical structure allows for dramatic weight loss without dieting.

Therefore, applicant submits that it is clear beyond doubt that claim 37 recites novel features and provides multiple new and unexpected health benefits and thus clears Ringe under Sec. 103.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO ASSUMED UNWORKABILITY**

Up to now those skilled in the art have thought fiber could not be used to provide dramatic weight loss without the need to diet. Applicant's novel physical structure allows for consumption of 7 or more grams of very specific fibers with very specific physical characteristics and biological functions that provides dramatic satiety and remains well tolerated. In addition Ringe and those skilled in the art, have felt fiber especially in large doses requires vitamin and mineral supplementation. Applicant's invention due to its novel physical characteristics makes vitamin and mineral supplementation unnecessary.

Those skilled in the art never thought that metabolic syndrome could be prevented or treated with high fiber supplements. Applicant has found this new use

Therefore, applicant submits that it is clear beyond doubt that claim 37 recites novel features and provides solutions to providing ultra-high fiber (at least 7 grams per serving) safely to a mammal and provides dramatic weight loss without dieting. Additionally, vitamin and mineral supplementation is unnecessary. Applicant's novel structure can be used to treat or prevent metabolic syndrome. Applicant's invention is unobvious over Ringe and thus clears Ringe under Sec. 103.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS A COMMERCIAL SUCCESS**

Applicant's invention is a commercial success and this has been based on word-of-mouth excitement over the weight loss and health benefits. Applicant asks examiner to review proof offered in Rule 132 Declaration.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS IN A CROWDED ART**

At present there are multitudes of prescription drugs, and over the counter nutritional supplements, and foods that claim to give weight loss. The large number of available options shows that no drug, product or food works very well, and that is why so many exist.

Treatment for obesity is a billion dollar industry and a very crowded art. Applicant's invention produces dramatic weight loss without the need for dieting, stimulants, or exercise. Ringe does not teach weight loss. Applicant's numerous benefits should individually be regarded as significant in a crowded field.

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Ringe. This clearly proves beyond doubt that applicant's novel structure is unobvious over Ringe under Sec. 103.

### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO OMISSION OF AN ELEMENT(S)**

As noted above, Ringe's ready-to-eat cereal has a composition that has numerous ranges and restrictions as provided above. Ringe also requires low shear blending and cooking of the cereal.

Applicant does not require insoluble fiber, (strictly the husk of psyllium), syrup, salt, or a vitamin blend as required in Ringe. Applicant does not require low shear blending or cooking. Thus several elements are omitted. Thus applicant's physical structure is novel over Ringe.

The two structures are very different and applicant's invention is therefore novel in that it does not require all elements fundamental to Ringe. Therefore, applicant submits that it is clear beyond doubt that claim 37 recites novel and unobvious structure over Ringe and clears Ringe under Sec. 103

### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE LACK OF IMPLEMENTATION**

If applicant's invention was in fact obvious, because of its advantages, Ringe and others skilled in the art surely would have implemented it by now. The fact that Ringe and others have not implemented applicant's invention despite its great advantages, indicates that it is not obvious. Ringe's intention was to develop a ready-to-eat cereal that was high in soluble fiber especially psyllium and that tastes good. He requires a minimum of 15 elements to do this and special processing. Applicant's invention requires only 4-5 ingredients and no special processing. If Ringe could have made a simpler composition for his ready-to-eat cereal he would have done it. The fact that applicant's invention omits many elements shows that it is novel and unobvious.

Therefore, applicant submits that it is clear beyond doubt that method claim 37 recites novel and unobvious structure over Ringe and clears Ringe under Sec. 103

## **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO MISUNDERSTOOD REFERENCE**

Applicant believes all claims show that invention is unobvious and that Ringe as a reference does not apply to applicant's invention.

Ringe's invention only deals with a ready-to-eat cereal that can come in different cereal sizes and shapes (shreds, biscuits, flakes, puffs). (Column 7, lines 65-68.) (Column 8, lines 1-5 .)

Applicant does not teach the necessity of insoluble fiber, nor the need for high level of psyllium. Applicant specifically teaches a beverage, pudding and snack bar.

Applicant respectfully feels that Ringe as a reference was misunderstood in respect to applicant's invention. Applicant believes that all claims now proves the applicant's novel structure is unobvious over Ringe under Sec. 103.

**Applicant respectfully feels Ringe is misunderstood as Ringe's teaching of total cholesterol reduction is not at all similar to applicant's teaching of pan-lipid lowering.** Reduction of total cholesterol is near- meaningless, as it does not correlate with reduction of cardiovascular disease or health benefits as applicant has described in detail above. One cannot assume that just because a composition contains soluble fiber, that it will lower cholesterol. Furthermore, total serum cholesterol varies by as much as 30 points in a 24 hour period making it an unreliable measure of serial readings. Applicant respectfully notes that Ringe's invention may not even lower total serum cholesterol as Ringe requires a low fat, low cholesterol diet as part of his method. Since this type of diet can cause the serum cholesterol to drop, there is no proof his invention does anything. There is no proof Ringe improves cholesterol in any meaningful way nor that he offers any health benefit.

Therefore, applicant submits that Ringe is misunderstood because applicant's physical structure is novel over Ringe, applicant does not require special processing of Ringe, and because Ringe's supposed reduction of total cholesterol is not similar to applicant's very valuable improvement in pan-lipid parameters that offer consistent correlation with the reduction in cardiovascular disease. It is clear beyond doubt that method claim 37 recites novel and unobvious structure over Ringe and clears Ringe under Sec. 103.

### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PROVIDES A SOLUTION OF LONG-FELT AND UNSOLVED NEED**

The conditions of overweight and obesity are an epidemic in the United States. Two thirds of Americans are overweight and at least 1/3 are obese. The great variety of weight loss pills, prescriptions, diet programs and regimens provide little if any consistent weight loss. The sheer fact that so many options exist prove that no one diet plan works well. Applicant's invention provides the solution to the obesity problem. The invention allows for dramatic weight loss without the need to diet. Since foods are not restricted, weight loss remains easy and consistent.

Applicant's invention also offers a natural nonprescription solution to a variety of health conditions and diseases. Applicant's invention can help prevent or treat the variety of conditions listed in claim 37. Many times medications can be reduced or even eliminated, two such examples are hypertension and diabetes.

Applicant's novel physical structure solves a long-felt unsolved need to have dramatic weight without food restriction. It is clear beyond doubt that method claim 37 recites novel and unobvious structure over Ringe, and clears Ringe under Sec. 103.

### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT SOLVES A DIFFERENT PROBLEM FROM RINGE**

Ringe teaches special ingredients, ratios and percentages are necessary to make a ready-to-eat cereal organoleptically pleasing. Applicant teaches that 3 very specific fibers, each with their own specific physical and biological characteristics are necessary to make an edible food product that can exist as a zero calorie food product and can provide numerous health benefits. Ringe teaches how to make a ready-to-eat cereal taste good, whereas applicant is teaching how very specific fibers can be used for dramatic weight loss and a variety of other health benefits. Each invention solves a different problem.

Applicant solves a problem different than Ringe also by teaching a different method claim. Ringe teaches how to make a ready-to-eat cereal, and how to lower total serum cholesterol. Applicant teaches a novel ultra-high fiber composition that contains 7 or more grams of fiber per serving and various methods of treating or reducing the risk of developing a variety of diseases. It is clear beyond doubt that method claim 37 recites novel and unobvious structure over Ringe, solves a problem different than Ringe, and clears Ringe under Sec. 103.

Applicant respectfully refers examiner to *In re Wright*, 6 USPQ 2d 1959 (1988) and *In re Dillon* 13 USPQ2d 1337 (1989). Whereby an inference of unobviousness in favor of the applicant, and the practical result that the PTO's prima facie determination of obviousness was over-ruled and the burden of proof shifted from the applicant to the PTO.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO LACK OF CONVINCING REASONING**

Applicant respectfully does not see a convincing line of reasoning as to why the claimed subject matter as a whole, including the differences noted over the prior art, would have been obvious.

**Ringe teaches a complex composition that has numerous ranges and ratios. His invention requires a minimum of 15 ingredients and special processing.** All of his teachings are necessary to make his food product taste good. Specifically he teaches the need for insoluble



fiber and the ratio of soluble fiber to insoluble fiber of 1 to 5:1. Applicant respectfully does not understand how his invention could be anticipated by Ringe. **If Ringe teaches the necessity of elements, ratios and percentages, how can one anticipate an invention that does not include his teachings. Furthermore, applicant teaches a beverage, pudding and snack bar, Ringe teaches only a ready-to-eat cereal.** How could it be anticipated that omitting several necessary requirements of Ringe, would lead to a food product that would offer real cardiovascular risk benefits and pan-lipid improvement, when Ringe cannot even prove his invention alone can reduce total serum cholesterol- a meaningless number. The fact that Ringe's or other inventions contain soluble fiber does not mean it will lower LDL cholesterol or triglycerides. Even if Ringe did lower total serum cholesterol it should not imply that cardiovascular risk is reduced. Applicant respectfully does not see how Ringe or other known patents could have anticipated applicant's novel physical structure and variety of health benefits. In the art of weight loss, no previous art has shown fiber could result in dramatic weight loss, and without the need for dieting. No one could have anticipated a fiber invention containing 7 or more grams of fiber per serving not requiring supplementation with vitamins and minerals, nor could they have anticipated such a high fiber per serving food product would be so well tolerated.

Applicant respectfully does not feel that citing Ringe provides any convincing reasoning toward obviousness of applicant's invention. Applicant does not understand how anyone reading Ringe could have anticipated applicant's invention or would have come up with novel physical structure or new uses that applicant has provided. It is clear beyond all doubt that applicant's claim 37 clears Ringe over Sec. 103.

## **THE DEPENDENT CLAIMS ARE A FORTIORI PATENTABLE**

**Since independent claims 24 and 37 are shown to recite novel and unobvious subject matter over Ringe, all the dependent claims listed above are a fortiori patentable over Ringe.**

Moreover applicant submits that dependent claims 25-36, and 38-41, are independently patentable over Ringe for the following reasons.

Claim 25 provides specific gram ranges for the guar, oat, and psyllium and does not require a sweetener. Ringe requires psyllium but does not require, guar and oat. Ringe requires an insoluble fiber and at least 3 grams of soluble fiber per ounce of cereal. The soluble to insoluble fiber ratio must be 1 to 5:1. Applicant does not make these requirements necessary. This proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 26 shows nutritional supplement of claim 24 can exist as a liquid, semisolid or solid edible food product. Ringe teaches only a ready to eat cereal not a liquid, powder, pudding, or snack bar. These differences in physical structure proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 27 teaches at least one additional fiber can be added. Ringe teaches fibers can be added but the soluble to insoluble fiber ration must be 1 to 5:1. Applicant has no soluble to insoluble ratio restrictions, nor the requirement of an insoluble fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 28 was not rejected by examiner under Sec. 102. Applicant teaches how to make a beverage, Ringe does not teach this.

Claim 29 currently amended teaches that semisolid and solid food products can be made. Ringe teaches only ready-to-eat cereal. These structural differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 30 further defines the flavoring agent that is a necessary part of applicant's supplement. Applicant states flavoring agent is a sweetener. Applicant can make his invention with one sweetener. Ringe provides examples that use more than one sweetener. Typically Ringe makes a slurry. Applicant's invention can have zero calories, Ringe does not teach this and his sweeteners and syrups add calories. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 31 teaches that additional ingredients that improve visual or organoleptic appeal can be added. Ringe does not discuss thickening agents, thinning agents, or emulsifiers. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 32 was not rejected by examiner under section 102. Applicant teaches an antioxidant can be added. Ringe does not.

Claim 33 was not rejected by examiner under section 102. Applicant teaches an tea can be added. Ringe does not.

Claim 34 teaches vitamins, minerals, coenzymes, plant polyphenols, electrolytes etc. can be added but are not necessary as applicant's invention does not cause vitamin and mineral deficiencies. Ringe teaches vitamins and minerals are needed to prevent vitamin and mineral deficiencies that are caused by the fiber in his invention. Ringe teaches these vitamins and minerals are a replacement, not as a method of treating or reducing risks of various diseases. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 35 teaches at least one caloric ingredient can be added including carbohydrates, fats, and proteins. Ringe teaches various fibers and carbohydrates can be added. Ringe does not teach protein addition to his ready-to-eat cereal. Ringe does teach fats can be added but restricts them to 4% of the final weight of the product. Applicant does not have these restrictions. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 36 shows a preferred alternate embodiment with green tea, multianthocyanadins, folic acid, pyridoxine, locust bean gum, pectin, and at least one sweetener and flavoring agent. Ringe teaches pectin can be used as well as some vitamins but does not specify which ones. Ringe does not teach green tea, multianthocyanadins, and locust bean gum. This shows very different structure than Ringe. Ringe teaches very specific fibers and locust bean gum is not one of them. These differences, the differences number, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claims 38 and 39 were not rejected under Sec. 102

Claim 40 teaches at least one additional fiber can be added. Ringe teaches fibers can be added but the soluble to insoluble fiber ration must be 1 to 5:1. Applicant has no soluble to insoluble ratio restrictions, nor the requirement of an insoluble fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 41 teaches vitamins, minerals, coenzymes, plant polyphenols, electrolytes, substances that induce weight loss, etc. can be added but are not necessary as applicant's invention does not cause vitamin and mineral deficiencies. Ringe teaches vitamins and minerals are needed to prevent vitamin and mineral deficiencies that are caused by the fiber in his invention. Ringe

teaches these vitamins and minerals are a replacement, not as a method of treating or reducing risks of various diseases. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

**THE REJECTION OF CLAIMS 24-27,29-31, 34-36, 37,40-41, UNDER SEC. 103 (a) IS OVERCOME**

**INDEPENDENT CLAIMS 65 AND 70 CLEAR RINGE OVER SEC. 102 (b).**

Claims 65-74 are new claims that resulted when claim 37 was split into more than one claim. At examiners advice applicant has split claim 37 into independent claims 65 and 70 and each of the dependent claims to 37 have been newly added as numbers 66-69 and 71-74.

**Though claims 65 and 70 were not rejected, they are discussed here as they did originate from claim 37 which was rejected.**

Claim 65 is a new claim that was part of claim 37. Applicant thanks examiner for suggestion to break claim 37 into separate claims. Claim 65 shows a method of improving the cardiovascular health of a mammal. The claim shows the method as orally consuming the nutritional supplement, achieving at least one health benefit related to cardiovascular disease, additionally improving serum markers of cardiovascular disease, and additionally limiting the absorption of dietary cholesterol and fats.

New claim 70 was not rejected, but was part of previously presented in claim 37 which was rejected under Sec. 102 as being anticipated by Ringe. Applicant thanks examiner for suggestion to break claim 37 into separate claims. Claim 70 shows a method of improving the

health of a mammal through limiting orally ingested toxins. The claim shows the method as orally consuming the nutritional supplement, binding of the supplement to the toxins which thereby limits absorption, and speeding transit of toxins through the gastrointestinal tract

## **NEW INDEPENDENT CLAIMS 65 AND 70 UNDER SEC. 102 (b) ARE OVERCOME**

Claims 65-74 are new claims that resulted when claim 37 was split into more than one claim. At examiners advice applicant has split claim 37 into independent claims 65 and 70 and each of the dependent claims to 37 have been newly added as numbers 66-69 and 71-74.

Applicant respectful of examiner's time is treating both independent claims under this section in order to prevent a more lengthy amendment.

Though 65 claim was not rejected, it is discussed here as it did originate from claim 37 which was rejected under Sec 102 (b) as being anticipated by Ringe.

Claim 65 is a new claim that was part of claim 37. Applicant thanks examiner for suggestion to break claim 37 into separate claims. Claim 65 shows a method of improving the cardiovascular health of a mammal. The claim shows the method as orally consuming the nutritional supplement, achieving at least one health benefit related to cardiovascular disease, additionally improving serum markers of cardiovascular disease, and additionally limiting the absorption of dietary cholesterol and fats.

Claim 70 was not rejected, but was part of previously present claim 70 which was rejected under Sec. 102 as being anticipated by Ringe. Claim 70 is a new claim that was part of previously presented claim 37. Claim 70 shows a method of improving the health of a mammal through limiting orally ingested toxins. The claim shows the method as orally consuming the nutritional

supplement, binding of the supplement to the toxins which thereby limits absorption, and speeding transit of toxins through the gastrointestinal tract. .

## **APPLICANT'S INVENTION**

Applicant's invention is orally administered nutritional supplement for ingestion by mammals containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent.

Applicant's novel physical structure including specific fibers with specific physical and biological characteristics allows for applicant's supplement to be delivered in a beverage, semisolid, or solid form. Additionally, the specific fibers with their specific physical characteristics allows for zero calorie food products to be made.

Applicant's invention is novel in that its physical structure allows a mammal to consume more than 7 grams of fiber per serving in safe, easy, convenient and palatable manner without significant side effects.

Applicant's invention is novel in that its physical structure allows a mammal to consume ultra-high fiber (at least 7 grams per serving) without the need to replace minerals and nutrients that high fiber is known to sequester or block the absorption of.

Applicant's invention is novel in that its physical structure as the specific fibers with their specific physical characteristics provide strong and long lasting satiety.

Applicant's invention is novel in that it provides many new uses. With respect to claims 65 and 70, invention provides multiple cardiovascular benefits and reduced toxin exposure to orally consumed toxins.

Applicant's invention is novel in that it provides numerous new uses for reduction in cardiovascular risk and for limiting ingested toxin exposure. Applicant's novel physical structure and composition allows for consumption of very high doses of fiber that are well tolerated by mammals.

## **Ringe**

Ringe (US Patent 5,026,689)

Ringe's invention is a ready-to-eat cereal that is high in soluble fiber especially psyllium husk and is organoleptically pleasing. Ringe also teaches a method of preparing the cereal and a method of reducing total cholesterol. Ringe does not teach reduced toxin exposure and he does not teach the numerous cardiovascular benefits that applicant does. Reducing total cholesterol has little correlation with cardiovascular disease. Applicant believes Ringe should not be credited even with total cholesterol reduction when Ringe cannot even lower total cholesterol unless a low fat, low cholesterol diet is followed.

Ringe's invention is a complicated composition:

1. Psyllium husk only and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.)
2. Starchy cereal 20-80% of cereal composition. (Column 4 , lines 31-34.)
3. Insoluble fiber
4. Soluble/Insoluble fiber ratio of 1 to 5:1
5. Soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Column 8 , lines 16-27 .)
6. Salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.)
7. Syrup (Malt or Corn) Malt 1%-8% by dry weight basis (Column 6 , lines 54-57 & exampl-3).
8. Vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.)
9. Fat content limited to 4% or less. (Column 6 , lines 35-39 .)
10. Fructose restriction to less than about 15%. (Column 6 , lines 20-23.)
11. At least one sweetener (Examples 1-4)



12. Minimum of 15 ingredients (Examples 1-4).
13. Cereal to have a moisture content of 1%-3%. (Column 7 , lines 62-65 .)

The composition of the ready-to-eat cereal is defined by the weight ratio of soluble to insoluble fiber and maximum fat and fructose levels. The ready-to-eat cereals are further essentially defined by limited concentrations of fructose. (Column 2 , lines 49-56 .)

In one method aspect of preparing the ready-to-eat cereal, the methods essentially compromise blending the cereal ingredients with controlled amounts of water, COOKING the mixture to form a cooked cereal, forming the cooked cereal into a cooked cereal dough with LOW SHEAR MIXING, and forming the cereal dough into pieces and drying the cereal pieces to form the present ready-to-eat cereals. (Column 2 , lines 60-68 .)

## **APPLICANT'S INVENTION HAS GENERAL DIFFERENCES OVER RINGE**

Applicant's invention is for mammals. Ringe is for humans. (Column 3 , line 3 .)

Applicant's nutritional supplement invention can exist as a liquid (beverage), semisolid (pudding) or solid (snack bar). Ringe exists only in a ready-to-eat **cereal** form, but does provide for various shapes----all shapes strictly related to cereals (i.e., puffed, flake, shreds, biscuits etc). (Column 7-8 , lines 66-68 and 1-6 .) Ringe does teach that different "cereal forms" can be made, but his invention only deals with a ready-to-eat cereal. Ringe does not teach a liquid, pudding, or snack bar.

Overview Differences in structure Ringe vs. Applicant.

1. Ringe : Psyllium husk only and makes up 5%-37% of the cereal weight (Column 4 , lines 4-19.)

Applicant can use any form of psyllium and can use less than 5% by dry weight.

2. Ringe: Starchy cereal 20-80% of cereal composition. (Column 4, lines 31-34.)

Applicant teaches oat fiber is necessary but distinguishes oat fiber by mesh size. Applicant's invention can have less than 20% or more than 80% oat fiber.

3. Ringe: Insoluble fiber

Applicant believes Ringe incorrectly labels psyllium husk as a soluble fiber and then ties several important points to psyllium providing the soluble fiber in his invention. Applicant believes that psyllium husk is primarily an insoluble fiber.

4. Ringe : Soluble/Insoluble fiber ratio of 1 to 5:1

Applicant's novel structure is not based on soluble/insoluble fiber ratios. Applicant's invention can be much higher than a 5:1 ratio.

5. Ringe : Soluble fiber 11%-30% of cereal weight (3-6 grams per ounce) (Column 8, lines 16-27.)

Applicant's novel structure is not tied to soluble fiber percentages and in most cases has soluble fiber much higher than 30%.

6. Ringe: Salt 0.1-2% (Column 6 , lines 51-54 and additionally in all 4 examples.)

Applicant does not teach salt as part of his novel structure.

7. Ringe: Syrup (Malt or Corn) Malt 1%-8% by dry weight basis (Column 6 , lines 54-57 & example 1-3).

Applicant does not teach malt as a necessary component of his novel structure and certainly does not tie the novel structure to a malt content of 1%-8%.

8. Ringe: Vitamins added due to insoluble fiber adversely affecting mineral and vitamin absorption. (Column 6 , lines 58-68.)

Applicant does not require vitamins as applicant's novel structure does not inhibit absorption of vitamins or minerals. Applicant also questions how supplementing vitamins by topically applying them (Column 7, lines 1-3) to a cereal overcomes the insoluble fibers ability to absorb them. (Just because you add more vitamins, doesn't mean that the insoluble fiber in the cereal won't still prevent absorption of the vitamins and minerals that have been topically applied to the cereal.)

9. Ringe: Fat content limited to 4% or less. (Column 6 , lines 35-39 .)

Applicant's novel structure does not have any fat content restraints. Applicant's invention can contain much more than 4% fat.

10. Ringe: Fructose restriction to less than about 15%. (Column 6 , lines 20-23.)

Applicant's invention does not require any fructose, yet teaches no restrictions on fructose.

11. Ringe: At least one sweetener (Examples 1-4)

Applicant teaches that a flavoring agent is a necessary component of the novel structure but that flavoring agent can be a non-sweetening flavoring agent. Applicant teaches Sucralose is the preferred sweetening agent when used. Ringe does not teach sucralose but rather aspartame and potassium acesulfame (Column 8, lines 6-14 .)

12. Ringe: Minimum of 15 ingredients (Examples 1-4).

Applicant teaches a minimum of 4-5 ingredients are necessary to make the invention.

13. Cereal to have a moisture content of 1%-3%. (Column 7, lines 62-65 .)

Applicant does not teach any moisture content and does teach the restriction of 1%-3%.

Applicant's invention can be made with a minimum of 4-5 ingredients. Ringe needs a minimum of 15 ingredients.

Applicant's novel structure requires a flavoring agent but not specifically a sweetener. Ringe requires one or more sweeteners. (Examples 1-4).

Applicant has no restrictions on fructose and his invention can have either no fructose or unlimited fructose. **Ringe's invention is limited to 5% (abstract)**. "Care should be taken to respect the FRUCTOSE concentrations described above. (Column 8 , lines 14-15 .) "However, it is important that the total fructose content of the ready-to-eat cereal, including the fructose contained in the cereal composition as well as the fructose fraction of any sucrose collectively be limited to less than about 15% of the ready-to-eat cereal....The restriction of fructose content includes both any fructose in the base cereal and any fructose associated with any sugar coating. " (Column 6 , lines 11-20 .)

Applicant's nutritional composition does not teach a ratio of soluble to insoluble fiber. Ringe teaches that the ratio of soluble fiber to insoluble fiber is 1 to about 5:1. Applicant does not teach a soluble to insoluble fiber ratio and can have soluble to insoluble fiber ratios of much higher than 5:1.

Ringe claims the psyllium the "The present invention resides in part in the particular selection of psyllium as THE soluble fiber source. (Column 1 , lines 49-58 )"

Ringe teaches that high levels of psyllium are needed and that only psyllium husk is needed.

"The present invention relates to ready-to-eat cereals containing high levels of psyllium to methods for their preparation and to methods of reducing blood serum cholesterol by consumption of such cereals. In addition to conventional cereal ingredients, the present cereals additionally compose psyllium and insoluble fiber. " (Column 3 , lines 11-16 .) " As used in the present invention, the noun "psyllium" is meant to refer to psyllium husks and not to psyllium seed or psyllium seed gum. Psyllium seed gum is not intended to be embraced herein by the term psyllium. (Column 3 , lines 44-48 .)

**Applicant teaches that any form of psyllium can be used (specification) and does not require high doses of psyllium.** Applicant includes psyllium in his invention but provides more guar and Oat as the soluble fiber source.

Applicant's invention strictly **requires the composition to contain oat fiber**, Ringe's invention can be made without oat fiber ( column 10, Example 2).

Ringe teaches the importance of limiting fructose. Applicant does not teach any restriction on fructose.

Ringe teaches a low shearing process is necessary during admixing and cooking. (Column 7 , lines 7-11 .) Applicant does not teach a low shearing process, nor the need to cook.

Ringe requires **between 15 and 19 ingredients** to make his invention based on the ingredient table listed in all the examples. Applicant can make his invention with as **few as 4 ingredients**.

**Ringe requires a dry base blend requiring a minimum of 8 ingredients (Example 2, a malt syrup blend, and a sweetener. Applicant's invention requires only 3 ingredients and a flavoring agent. The fact that applicant's invention omits elements found necessary for Ringe, indicates novelty.**

## **INDEPENDENT CLAIMS 65 AND 70 RECITES NOVEL PHYSICAL FEATURES OVER RINGE UNDER SEC. 102.**

Claim 65 and 70 shows applicant's invention is orally administered nutritional supplement for ingestion by mammals containing at least 7 grams of fiber per serving comprising a mixture guar, oat, and psyllium fibers plus at least one flavoring agent. Applicant's nutritional supplement can exist as an edible food product that is liquid, semisolid, or solid. Applicant teaches specifically a beverage, pudding and snack bar. Each can exist as a zero calorie food product. The oat, guar, and psyllium all have very specific specifications, physical and biological properties. This novel structure allows for edible food products to be made with very few ingredients and minimal processing. In addition, the novel structure with the physical properties allows for several new uses.

Ringe's invention deals only with a ready-to-eat cereal that can exist in different cereal sizes and shapes. Ringe requires a minimum of 15 ingredients to make his cereal and very specific processing to make it. Ringe has numerous ratios, percentages, and requirements **all necessary to provide a good tasting cereal**.

Applicant's invention's ability to provide very high doses of fiber in a unit dose of administration (serving) without inert carriers, binders, lubricants, syrups, salts, or excipients is novel. Applicant's novel physical structure based on fibers with specific physical and biological characteristics provides very important, valuable, and unexpected new results that dramatically improve mammals' (and especially a human's) health. In relation to claim 65 and 70, numerous cardiovascular risks are reduced and invention can be used to limit ingested toxins and speed their delivery out of the body. This clearly proves applicant's novel structure is unobvious under Ringe.

Applicant's invention is physically different and does not require Ringe's processing or numerous ingredients. The final edible food product form differs as well.

**Therefore, applicant submits that it is clear beyond doubt that claim 65 and 70 recites novel physical features over Ringe and thus clears Ringe under Sec. 102**

## **CLAIM 65 AND 70 ALSO CLEAR RINGE UNDER SEC. 102 AS APPLICANT'S INVENTION HAS NEW USES.**

Applicant's invention with its unique physical structure has a number of new uses not anticipated by Ringe or others. These new uses show novelty of applicant's invention. Several new uses are discussed above. In relation to claims 65 and 70 applicant teaches these new uses:

### **1. Dramatic weight loss without dieting or exercising**

Applicant's invention provides dramatic weight loss without the need to diet or to exercise. The commercial success of the product is proof. No other weight loss invention allows people to eat whatever they want and not exercise. Weight loss reduces cardiovascular risk in mammals that are overweight. This is one way that applicant's invention can reduce cardiovascular risk.

### **2. Dramatic cholesterol benefits**

Applicant's invention provides very dramatic cholesterol benefits. NCEP guidelines state that 10 grams of soluble fiber daily can give a 5% reduction in LDL cholesterol. Applicant's invention had demonstrated up to a 100 point or 60% reduction in LDL. In addition, applicant's invention has demonstrated up to a 56% increase in HDL and up to an 82% decrease in triglycerides. Applicant provided proof of these claims previously as part of Rule 132 Declaration submitted with Amendment A. These dramatic benefits could not have been anticipated.

3. Dramatic cholesterol benefits in people regardless if a low fat, or low cholesterol diet is followed.

Ringe's invention teaches 5%-20% reductions in total serum cholesterol. . Ringe himself states it only works in people with a cholesterol greater than 220 mg/dl, provides at most **a 10% reduction**, and only if the person is on a **low fat, low cholesterol diet for at least 6 weeks**. (Column 8 lines 46-50.) This is only if the person has an elevated LDL cholesterol >220mg/dl and only if the individual follows a low fat and low cholesterol diet for 6 weeks. Applicant believes Ringe's invention should not be credited at all with a method of reducing cholesterol as the low fat, low cholesterol diet alone could be the sole reason accounting for the reduction. **The fact that Ringe requires 6 weeks of a low fat, low cholesterol diet shows that the effect of the diet are reducing total cholesterol not his invention.** Applicant, a board certified internal medicine physician and expert who teaches other doctors advanced cholesterol evaluation and management also notes that reductions in total cholesterol are not necessary meaningful. Applicant teaches his patients to never use the total cholesterol value for any reason. Applicant notes that the day to day fluctuations could be 30 points or more (from one day to the next without any changes taking place in an individual's diet or exercise). Total cholesterol has proved to be an unreliable measurement tool and should not be use. Most importantly total cholesterol is not correlative with heart disease.

Applicant's invention provides dramatic cholesterol benefits and without following any diet. Most individuals find it extremely hard to follow a low fat and low cholesterol diet. Applicant's invention provides great benefits without following the low fat and/or low cholesterol diet.

4. Dramatic cholesterol benefits even for people with normal baseline cholesterol.

Applicant provides dramatic cholesterol benefits regardless of what baseline cholesterol numbers are.

Ringe teaches cholesterol reduction only if the LDL cholesterol is greater than 220 mg/dl.

5. Treatment and prevention of metabolic syndrome

Ringe teaches nothing about metabolic syndrome.

Applicant's invention through its weight loss and other mechanisms provides a treatment for metabolic syndrome. This provides a dramatic reduction in cardiovascular disease.

6. Treatment and prevention of glucose intolerance and diabetes.

Ringe: Teaches nothing about glucose intolerance and diabetes.

Applicant's invention improves glucose metabolism and reduces risk of developing insulin resistance, glucose intolerance, and diabetes. Applicant's invention can treat insulin resistance, glucose intolerance, and diabetes. Applicant provided information in specification and Rule 132 Declaration previously. Reducing insulin resistance and improving glucose metabolism provides dramatic reductions in the risk of cardiovascular disease.

7. Treatment and prevention of cardiovascular disease.

Ringe: Teaches nothing about cardiovascular disease.

Applicant: Teaches invention treats or reduces risk of developing cardiovascular disease by multiple mechanisms including lowering LDL cholesterol, raising HDL cholesterol, lowering triglycerides, **lowering high sensitivity C-reactive protein, lowering homocysteine, reducing cardiac inflammation, improving glucose metabolism, reducing body weight, and treating metabolic syndrome.**

8. Reducing ingested toxin exposure



Applicant's invention can greatly reduce the dangers of ingested toxins. Applicant's invention binds to toxins in the gastrointestinal tract and minimizes toxin exposure by at least two methods. Applicant's invention binds to toxins and slows or prevents their absorption into the body. Applicant's invention also speeds transit time, so that toxins whether bound or not to applicants nutritional supplement will be pushed through the gastrointestinal tract at an accelerated pace.

**Applicant's invention is novel as it provides several new uses over Ringe.**

Applicant's invention differs from Ringe's cholesterol reduction in several ways.

1. Applicant's invention lowers cholesterol even if person does not have cholesterol greater than 220 mg/dl.
2. Applicant's invention does not require any low fat or low cholesterol diet.
3. Applicant's invention is for mammals and not limited to people.
4. Applicant's invention dramatically improves the individual cholesterol components that make up the total cholesterol number not just total cholesterol. Thus providing real reduction in cardiovascular risk.
5. Applicant's invention treats high sensitivity C reactive protein and cardiac inflammation.
6. Applicant's invention treats elevated homocysteine levels, thereby reducing cardiovascular risk.
7. Applicant's invention treats several risk factors for cardiovascular disease such as the conditions of overweight and obesity, insulin resistance, glucose intolerance, and diabetes, cardiac inflammation and elevated high sensitivity C reactive protein levels, elevated homocysteine, and hypertension. Ringe does not teach any of these.

Applicant has provided examiner with proof of dramatic cholesterol improvement with individuals who have taken applicant's invention in the previously submitted Rule 132 Declaration. Applicant has demonstrated up to a 60% drop in LDL, up to an 82% drop in triglycerides, and up to a 56% elevation in HDL cholesterol. In addition, applicant has provided proof of lowering high sensitivity C-reactive protein.

**Therefore, applicant submits that it is clear beyond doubt that applicant's invention is novel and provides several new uses over Ringe and thus clears Ringe under Sec. 102**

## **THE NOVEL PHYSICAL FEATURES OF CLAIM 65 and 70 ARE UNOBVIOUS OVER RINGE UNDER SECTION 103**

Claims 65-74 are new claims that resulted when claim 37 was split into more than one claim. At examiners advice applicant has split claim 37 into independent claims 65 and 70 and each of the dependent claims to 37 have been newly added as numbers 66-69 and 71-74.

Though claim 65 and 70 was not rejected, it is discussed here as it did originate from claim 37 which was rejected as being anticipated by Ringe.

Claim 65 and 70 are new claims that was split off of claim 37. Applicant thanks examiner for suggestion to break claim 37 into separate claims. Claim 65 shows a method of improving the cardiovascular health of a mammal. The claim shows the method as orally consuming the nutritional supplement, achieving at least one health benefit related to cardiovascular disease, additionally improving serum markers of cardiovascular disease, and additionally limiting the absorption of dietary cholesterol and fats. Applicant also shows in claim 70 how mammals can reduce ingested toxins through consumption of applicant's invention.

Applicant's invention uses specific fibers with specific physical characteristics and physical and biological properties. Applicant's novel physical structure allows **7 or more grams of fiber per serving** to be delivered in an edible food product that is well tolerated and provides numerous health benefits.

Applicant submits that the above novel physical features of claim 65 and 70- including the ultra-high fiber (at least 7 grams per serving) composition comprising three specific fibers guar, oat,

and psyllium each with specific physical characteristics and properties and the addition of at least one flavoring agent is unobvious over Ringe for a variety of reasons listed below.

Applicant notes that Ringe teaches a ready-to-eat cereal composition, method of making this ready-to-eat cereal, and a method of total serum cholesterol reduction. Applicant respectfully does not understand how applicant's invention could have been obvious or anticipated by Ringe. Applicant teaches a beverage, pudding and snack bar, not a ready to eat cereal. Ringe teaches numerous elements, ratios, and percentages that applicant does not teach. Ringe teaches that a low cholesterol and low fat diet when used with his invention, can lower total cholesterol not cardiovascular risk. Applicant respectfully does not see how Ringe's teachings would allow applicant to think he could make an invention without Ringe's necessities, that would provide uses that Ringe never even thought of including real beneficial lipid improvement that reduces cardiovascular risk without the need for a low fat, low cholesterol diet, and the ability to limit ingested toxins. The mere fact that applicant's invention can be made with 4-5 ingredients, where as Ringe requires a minimum of 15 indicates that applicant's invention could not have been anticipated by Ringe.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT PRODUCES UNEXPECTED RESULTS.**

Applicant's invention has novel physical structure comprising 3 guar, oat, and psyllium, each with their own specific physical characteristics, and administered in an ultra-high fiber (at least 7 grams per serving) dosage. The total fiber weight must be at least 7 grams per serving and must include a flavoring agent. Applicant, a board certified internal medicine doctor and expert in advanced lipid treatment has noted several unexpected results amongst patients and users of his invention.

- (a) Safe, fast, easy weight loss occurs even in individuals who claim they have failed all diets. **It is well accepted that weight loss in individuals who are overweight reduces an important cardiovascular risk factor.** It is unexpected to see weight loss in

individuals who have failed all other diets. Applicant has witnessed steady weight loss in his patients, and has received numerous comments regarding successful weight loss in individuals who have stated they failed all previous diets. Applicant's extremely high reorder rate is further proof of successful weight loss. Applicant's invention works better than other weight loss products and is safer because it does not contain dangerous stimulants. **Ringe's invention is not a weight reduction formula.** Ringe offers no method, means or proof his invention will even lead to weight loss. Applicant's invention produces safe and effective weight loss and is seen as a benefit over Ringe's invention.

- (b) Weight loss occurs without need for food restriction and exercise. All diets not using orally consumed stimulants combine food restriction and exercise as a necessary part of the diet. Applicant's invention promotes satiety that is long lasting and curbs appetite so that less food is consumed despite eating the individual's normal diet. Applicant believes novel physical structure allows weight loss to occur by other mechanisms described in specification as well. Applicant's invention works much better than other weight loss products because the need for will power to restrict certain foods is unnecessary, and the individual does not have to exercise. Applicant's invention is specifically designed to maximize health benefits of fiber especially weight loss and cardiovascular risk reduction.

- (c) Dramatic reduction in the risk of heart disease due to one or more factors including reversal of metabolic syndrome, weight loss, improvement in cholesterol, triglycerides, lipids, high sensitivity C-reactive protein and homocysteine. Applicant, a physician, has documented marked reduction in risk of cardiovascular disease in numerous patients, and users who have communicated with applicant. **Applicant has documented reversal of metabolic syndrome, spectacular weight loss, and improvement in all lipid parameters as well as non-lipid cardiac risk factors homocysteine and high sensitivity C-reactive protein. Applicant has documented new and unexpected results in improvement of lipid parameters.** American doctors are taught to observe national guidelines for treatment of lipid disorders. These guidelines are based on the National Cholesterol Education Program Adult Treatment Program III guidelines (NCEP

ATP III 2001 V 20-21) . NCEP ATPIII teaches that 5-10 grams of soluble fiber only can lower LDL by 5% (NCEP ATPIII V20-21). **Applicant has documented LDL drops of over 100 points or reductions of up to 60%. It is unexpected to achieve a 60% reduction in LDL cholesterol when national guidelines teach only 5% reduction.**

Additionally, applicant has documented **triglyceride reductions of up to 82%.**

HDL cholesterol, the good cholesterol, serves as a reverse cholesterol transport. The higher the HDL level, the lower the risk of heart disease. Each one point increase in HDL correlates with a 3-4% reduction in heart disease. Applicant has documented **HDL rises as high as 22 points**, this is **unexpected** as the NCEP ATP III guidelines (V-20) show that soluble fiber **reduces** HDL. "Some investigators report that the consumption of viscous (soluble) fiber ( provided by oats, barley, psyllium, pectin-rich fruit, and beans ) produces a **reduction** in HDL cholesterol concentration (Anderson 1995). Other reviews report little, no, or inconsistent effect on HDL cholesterol (U.S. Department of Health and Human Services 1996,1997a).

Applicant's unexpected dramatic cholesterol improvements have resulted in numerous patients reducing their cholesterol medication, or eliminating the need for them altogether. In the most dramatic cases, patients have eliminated the need for 3 cholesterol medications that were at maximum doses! Ringe does not teach his composition can reduce or eliminate the need for cholesterol medications. Ringe does not teach his invention can lower LDL cholesterol and triglycerides, or raise HDL cholesterol. Ringe only teaches a mild lowering of total LDL cholesterol can occur in humans with LDL cholesterols greater than 220mg/dl and ONLY if they follow a low fat and low cholesterol diet for at least 6 weeks. Applicant's invention provides dramatic benefits in ALL cholesterol parameters and without regard to baseline cholesterol or a low fat, low cholesterol diet. Applicant produces new and unexpected results over Ringe.

Applicant has documented dramatic improvement in reducing cardiac inflammation as judged by high sensitivity C- reactive protein levels. Applicant's formula has taken people in the two highest levels of inflammation and reduced them to the lowest levels of inflammation. This correlates with a quintile 4-5 improved to quintile 1 greatly reducing the risk in cardiovascular disease. Ringe does not teach anything about high sensitivity C-reactive protein. Applicant produces new and unexpected results over Ringe.

Ringe's invention regarding method of reduction of total serum cholesterol is meaningless, it does not provide reduction in cardiovascular disease. Total cholesterol has very little correlation with heart disease and that is why doctors do not use it in decision making. Total serum cholesterol can vary as much as 30- points in a 24 hour period, also making it an unreliable measurement tool. Ringe provides no method, means, or proof his actual composition would result in any lipid parameter improvement (beyond the total serum cholesterol reduction). Applicant's invention could not have been anticipated by Ringe because Ringe provided reduction in total cholesterol (not reduction in cardiovascular risk) only if a low fat, low cholesterol diet is followed for at least 6 weeks. Applicant could not anticipate that diet would not be necessary, nor that dramatic lipid improvement could happen based on Ringe or others. Furthermore, it is totally unexpected when national guidelines and research quote soluble fiber can reduce LDL by 5% to get up to 60% reductions. Furthermore, no researcher could have anticipated applicant's invention could reduce the need for cholesterol medications or eliminate the need all together, especially when an individual required maximum dose of 3 cholesterol medications.

**Ringe does not teach improvement in HDL. It is totally unexpected when national guidelines and research quote soluble fiber reduces HDL to get up to a 56% improvement.** Applicant produces new and unexpected HDL results over Ringe..

Ringe does not teach improvement in high sensitivity C-reactive protein. Applicant is unaware of research showing fiber lowers high sensitivity C-reactive protein yet applicant's invention has improved high sensitivity C-reactive protein in many individuals taking the invention, and some have received maximal improvement. Applicant produces new and unexpected results in high sensitivity C-reactive protein over Ringe.

Another new and unexpected result of applicant's invention is that vitamin and mineral supplementation is not needed. High fiber food products need to be supplemented with vitamins and minerals because the fiber blocks their absorption. Applicant's invention does not require any supplementation of vitamins and minerals.

Ringe teaches that a vitamin blend is needed with his invention in order to make up for vitamins and minerals lost through consumption of his invention. Each of his examples includes a vitamin blend. Applicant respectfully does not understand how coating vitamins on his invention (which blocks absorption of vitamins and minerals due to its insoluble fiber content, allows for absorption of those vitamins and minerals coated on the outside of the cereal. **It is also unobvious that ultra high fiber (7 grams or more per serving) could be delivered without supplemental minerals or nutrients.**

Ringe does not teach anything about toxin exposure. Applicant teaches a method of reducing toxin exposure through consumption of applicant's invention. This valuable new use could not have been anticipated or be obvious based on Ringe.

Applicant's novel physical structure produces several new, unexpected, and very valuable results over Ringe. These include safe, easy weight loss, and dramatic reduction in risk of cardiovascular disease, improvement in cholesterol, lipids, triglycerides, and high sensitivity C-reactive protein. Additionally, applicant's invention limits ingested toxins. This clearly

proves that applicant's novel structure of claims 65 and 70 are unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED UNWORKABILITY.**

It is unobvious that 7 or more grams of fiber could be delivered without vitamin and mineral supplementation, Ringe teaches a vitamin blend is necessary. Applicant overcomes the assumed unworkability by allowing an individual to safely consume 7 or more grams per serving one or more times daily and without the need for nutrient supplementation. Applicant **notes in over two year's worth of use, there have been no safety issues, no need to supplement minerals or nutrients, and users have had no serious side effects.**

It is unobvious that applicant's invention could have such a profound effect on lowering LDL cholesterol and triglycerides and raising HDL cholesterol. National guideline show that up to 10 grams of soluble fiber can give up to a 5% reduction in LDL, where as applicant's invention has produced up to a 60% LDL cholesterol reduction. It is unobvious that applicant's invention could lower high sensitivity C reactive protein. It is unobvious that dramatic weight loss could occur without diet restriction or exercise.

It is unobvious that applicant's invention could provide so many grams of fiber in an easy to swallow, well tolerated manner. It is unobvious that toxin ingested could be minimized by applicant's invention. Ringe does not teach treatment of ingested toxin exposure.

Applicant's invention's ability **to safely deliver a minimum of 7 grams of fiber per serving to a mammal without the need for nutrient supplementation and/or that applicant's invention could so dramatically improves lipid parameters and/or that applicants invention could significantly reduce ingested toxin exposure** clearly proves that applicant's novel structure is unobvious over Ringe under Sec. 103.



**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AS IT OVERCOMES ASSUMED INSOLUBILITY.**

Up to present, those skilled in the art have avoided high doses of fiber due to side effects, and concern about high fiber being dangerous through interfering with absorption of nutrients (Ringe column 1, lines 58-63).

Applicant, a board certified internal medicine physician, has communicated with numerous patients and buyers of his invention who take more than 14 grams of fiber per day, without significant side effects or any evidence of nutrient or mineral deficiency. Up to now, Ringe and others skilled in the art felt high dose fiber necessitated mineral and nutrient supplementation. Applicant's invention has solved this problem and removed the necessity for nutrient and mineral supplementation.

Applicant's invention's ability to deliver higher doses of dietary fiber (7 grams or greater of fiber per serving) safely and without danger, risk, or need for vitamin or mineral supplementation proves that applicant's novel structure is unobvious over Ringe under Sec. 103. Applicant respectfully believes Ringe did not test his invention, as he states up to 1.5g/kg of body weight can be consumed in one sitting. For an 80lb man this would equate to 120 grams of cereal and  $(120/28\text{g per ounce} = 4.3\text{ oz of cereal}) \times 7.7\text{grams fiber per oz} = 33\text{ grams of fiber}$ . Applicant sees no information regarding toleration of Ringe's invention especially if he uses his upper range of psyllium. As a medical doctor, applicant questions whether 33 grams of fiber in one sitting would be tolerated by a human especially if the fiber was high psyllium as Ringe teaches. Another fundamental problem is that Ringe teaches 1-1.5 g/kg body weight. Does a 300 lb man  $300\text{ lbs} = 133\text{ kg}$ ,  $\times 1.5\text{ grams/kg body weight} = 199.5\text{ grams of cereal}$  or 7.125 ounces of cereal, or  $(7 \times 7.7\text{g fiber per ounce} = \text{about } 55\text{ grams of fiber})$ . Applicant doubts 55 grams of fiber in one sitting would be tolerated especially if that fiber was high in psyllium. As a

physician applicant believes Ringe should have tied his ratio to ideal body weight not measured body weight.

Ringe teaches that his invention and a low fat, low cholesterol diet for 6 weeks can reduce total cholesterol by 10% in patient with serum cholesterol above 220mg/dl. Nowhere in Ringe's patent does he teach his invention will work without a low fat, low cholesterol diet. He never teaches weight reduction. Ringe provides no method, means, or proof that his composition improves the significant lipid parameters (LDL cholesterol, HDL cholesterol, and triglycerides). With Ringe composition these 2 benefits are unworkable. Applicant provides weight loss and significant lipid parameter benefits showing his novel structure has overcome unworkability.

Applicant shows how his invention can valuably aid mammals that orally ingested toxins. This is common problem daily in emergency rooms everywhere. Current protocols use charcoal and a laxative to help remove certain toxins. Applicant's invention offers the advantage of binding more toxins and limiting more absorption. This problem of using a nontoxic substance to limit oral toxin ingestion was previously thought to be unworkable and applicant has solved it.

Applicant's invention with novel physical structure allows delivery of at least 7 grams of fiber per serving, safely, and without risk or danger to the user. Applicant also provides dramatic weight loss and cardiovascular risk reduction/ cholesterol benefits for the user. Applicant provides a solution to obesity, dyslipidemia, ingestion of toxins, and the dangers of high fiber consumption proving that applicant's novel structure is unobvious over Ringe under Sec. 103.

#### **APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS DUE TO OMISSION OF ELEMENT(S)**

Ringe's invention requires a minimum of 15 ingredients to make his invention.

Applicant's invention omits many elements and requires only 4-5 ingredients to make a beverage, pudding or snack bar. Applicant has described in detail the multiple elements

omitted. Despite applicant's simpler invention, applicant produces dramatic cardiovascular disease reduction and the ability to limit orally ingested toxins.

Applicant's invention's omission of several of Ringe's elements proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS A COMMERCIAL SUCCESS.**

Previously submitted Declaration under Rule 132. Applicant has been successfully selling invention through word of mouth advertisement.

The fact applicant's novel physical structure has produced such dramatic benefits has lead to commercial success that proves Claims 65 and 70 are unobvious and clear Ringe over Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS IN A FIELD THAT IS A CROWDED ART.**

The benefits of fiber are well accepted. Fiber supplements are a crowded field, therefore any step forward however small should be regarded as significant. Ringe offers no meaningful improvement in cholesterol or reduction in cardiovascular risk. Even the best fiber regimen that researchers could postulate only offered a 5% reduction of LDL cholesterol (NCEP ATP III 2001 V20-21).

Applicant's invention as listed in claims 65 and 70 provides several steps forward over Ringe. Applicant's invention provides dramatic weight loss and cardiovascular risk reduction, as well as dramatic improvement in cholesterol, lipids, triglycerides, high sensitivity C-reactive protein, homocysteine, glucose metabolism, digestive diseases, and metabolic syndrome and provides a number of other health benefits including limiting absorption of orally ingested toxins.

Applicant's novel physical structure in claims 65 and 70 provides numerous health benefits over the crowded field of cholesterol reduction supplements, and proves without doubt that applicant's claims 65 and 70 show novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND OFFERS AN UNAPPRECIATED ADVANTAGE.**

Applicant's invention according to claim 24 offers several unappreciated advantages. Ringe therefore puts a "vitamin blend" into each of his examples.

Applicant's invention does not require vitamin or mineral supplementation. This offers a huge advantage as one does not need to worry that certain vitamins or minerals are being depleted and ultimately endangering the individual's health. In more than 2 years of selling his invention, applicant notes no vitamin, or mineral deficiencies or any health problems even when more than 34 grams of fiber of applicant's invention were taken daily. Ringe does not provide proof that topically applying a vitamin blend to his cereal can overcome the binding of those vitamins and minerals to his cereal.

Applicant's invention provides an ultra-high fiber (at least 7 grams per serving) supplement. This along with the novel structure, provides many unappreciated advantages. Ringe and others skilled in the art, could not have anticipated the dramatic weight loss, lipid benefits and other health advantages such as lowering of high sensitivity C-reactive protein. NCEP ATP III guidelines teach that soluble fiber at 5-10 grams per day provides only a 5 % reduction in LDL cholesterol. These guidelines also teach that HDL is usually lowered. Applicant's invention has lowered LDL by as much as 60% and typically raises the HDL. In a particularly dramatic case the HDL was raised 22 points (a 56% elevation). (Each HDL point increase is equivalent to a 3-4% risk reduction in cardiovascular disease). These dramatic benefits could not have been anticipated.

Ringe does not teach limiting absorption of orally ingested toxins. Applicant notes this is unappreciated advantage and unobvious over Ringe.

Applicant's invention's numerous unappreciated advantages provided over Ringe's fiber composition proves that applicant's novel structure of claims 65 and 70 are unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND HAS NOT BEEN IMPLEMENTED.**

Applicant's invention is novel and unobvious. If the invention were obvious, if the advantages were obvious, Ringe and those skilled in the art would have surely developed it by now. The fact that Ringe and those skilled in the art have never created applicant's invention indicates it is not obvious.

If Ringe or others could have demonstrated dramatic lipid improvements, dramatic weight loss, dramatic lowering of cardiovascular risk factors including high sensitivity C reactive protein, or reduced toxin ingestion, they surely would have made it by now.

The fact that applicant's invention was not previously created proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND QUOTED REFERENCE IS MISUNDERSTOOD.**

Applicant respectfully feels Ringe as a reference is misunderstood. Applicant provides a nutritional supplement that has novel structure and provides numerous health benefits. Ringe teaches how to make a ready-to-eat cereal that requires numerous elements, ratios, and percentages to taste good. Applicant teaches methods of dramatically improving a mammal's health. Ringe teaches that following a low cholesterol, low fat diet for 6 weeks and taking his

invention can lower total cholesterol, a meaningless number that does not correlate with cardiovascular disease. Applicant teaches pan-lipid lowering in a mammal, as well as dramatic cardiovascular risk reduction. Applicant also teaches how a mammal can limit ingested toxins through the use of applicant's invention.

Applicant respectfully feels that Ringe as a reference was misunderstood in respect to applicant's invention. Applicant's novel physical structure and the methods and benefits claimed in claims 65 and 70 prove applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND IS CONTRARIAN INVENTION OVER PRIOR ART**

Ringe teaches to make a ready-to-eat cereal that requires a minimum of 15 different ingredients. Ringe teaches the importance of specific ratios for psyllium, starchy cereal, and soluble to insoluble fiber. Ringe teaches oat fiber is not required. Ringe teaches that vitamin and mineral supplementation are necessary.

Applicant teaches that an ultra-high dose fiber at least 7 grams of fiber per serving can be made with as few as 4 or 5 ingredients and can be made into an edible food product that is well tolerated. Applicant teaches that oat fiber is a necessity to this composition. Applicant teaches his invention does not require vitamin or mineral supplementation.

Applicant's invention is contrarian to what Ringe teaches and therefore proves that applicant's novel structure is unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND BELIEVES RINGE IS A "PAPER PATENT".**

Applicant is a board certified internal medicine physician who has made other nutritional supplements and skin care products. Applicant is aware of most treatments for improving health and preventing disease, whether prescription, over the counter, or through a variety of marketing channels. Applicant is unaware of Ringe's invention in the market place and he believes it is not currently being made or sold and is in fact a 'paper patent'. Applicant believes Ringe's invention was never implemented or commercialized and therefore should be construed narrowly. As stated in office action page 9 first paragraph, Ringe fiber content is 7.2-7.7 grams per ounce and he teaches that an 80 kg. person would need about 3 ounces. Ringe teaches it can be eaten 1-3 times daily. In this example 22-23 grams of fiber would be consumed in one sitting. As listed above, following Ringe's formula could lead a person to attempt to consume about 45 grams of fiber high in psyllium in one serving. Applicant notes that this much fiber in one setting or even spread out through out the day, is usually tied to gastrointestinal complaints, bloating, cramping, and diarrhea. Applicant respectfully notes that Ringe does not teach how his product is tolerated and the dangers of consuming that much fiber at one time. Ringe notes that psyllium is a bulk laxative, obviously taking a lot of it would promote severe diarrhea. Applicant believes that Ringe is not credible in his psyllium or fiber per serving. Applicant believes Ringe's invention was never made.

To the contrary, applicant's invention is sold commercially and is commercially successful. Applicant has previously submitted a Declaration under Rule 132 to offer proof of applicant's health benefits.

Applicant believes Ringe's invention is a paper patent where as applicant's invention is commercially successful. Therefore, Ringe's invention should be construed narrowly and this proves that applicant's novel structure of claims 65 and 70 are unobvious over Ringe under Sec. 103.

**APPLICANT'S INVENTION IS NOVEL AND UNOBVIOUS AND NO CONVINCING REASONING IS PROVIDED.**

Applicant's supplement as listed in claim 65 and 70 is novel and unobvious and that is why it was never made before. Ringe teaches a minimum of 15 ingredients are needed, whereas, applicant notes that the edible food product can be made with 4 or 5 ingredients. Ringe's complicated ratio driven composition would not anticipate applicant's simpler to make composition, nor the added health benefits of applicant's invention. **Ringe's ratios, percentages, and ingredients are necessary to make an organoleptically pleasing food product, it cannot be obvious that not following his teachings would result in food products that are organoleptically pleasing and offer many new uses.**

Applicant believes claims 65 and 70 shows that invention is unobvious and that Ringe as a reference does not apply to applicant's invention and that no convincing reasoning exists as to the obviousness of applicant's invention.

Applicant respectfully does not see a convincing line of reasoning as to why the claimed subject matter as a whole, including the multiple differences noted over the prior art, would have been obvious thus proving that applicant's novel structure is unobvious over Ringe under Sec. 103.

## **NEW INDEPENDENT CLAIMS 65 AND 70 UNDER SEC. 103 (A) IS OVERCOME**

**THE NOVEL PHYSICAL FEATURE OF CLAIMS 65 AND 70 PRODUCES NEW AND  
UNEXPECTED RESULTS AND HENCE ARE UNOBVIOUS AND PATENTABLE  
OVER THESE REFERENCES UNDER § 103**

**THE DEPENDENT CLAIMS OF CLAIMS 65 AND 70 ARE A  
FORTIORI PATENTABLE**



Since independent claims 65 and 70 show novel and unobvious subject matter over Ringe the dependent claims 66-69, and 71-74 are a fortiori patentable over Ringe. Applicant also submits that dependent claims 66-69, and 71-74 are independently patentable over Ringe and should a fortiori be allowed.

Claim 66 teaches how to make a beverage. Ringe does not.

Claim 67 teaches method of making a semisolid or solid food product and then consuming with liquid to hydrate the fiber. Applicant's novel physical structure can be made with 4-5 ingredients, where as Ringe requires a minimum of 15. Applicant does not require insoluble fiber, Ringe does. Ringe does not teach the method of consuming the semisolid and/or solid with a liquid to hydrate the fiber. Therefore, applicant's claim shows novel physical structure and is unobvious and clears Ringe under Sec. 102 and 103.

Claim 68 teaches at least one additional fiber can be added. Ringe teaches fibers can be added but the soluble to insoluble fiber ration must be 1 to 5:1. Applicant has no soluble to insoluble ratio restrictions, nor the requirement of an insoluble fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 69 teaches additional ingredients can be added for health benefits including vitamins, minerals, coenzymes, plant polyphenols, electrolytes substance that induce weight loss etc. can be added but are not necessary as applicant's invention does not cause vitamin and mineral deficiencies. Ringe teaches vitamins and minerals are needed to prevent vitamin and mineral deficiencies that are caused by the fiber in his invention. Ringe teaches these vitamins and minerals are a replacement, not as a method of treating or reducing risks of various diseases. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103..

Claim 71 teaches how to make a beverage. Ringe does not.

Claim 72 teaches method of making a semisolid or solid food product and then consuming with liquid to hydrate the fiber. Applicant's novel physical structure can be made with 4-5 ingredients, where as Ringe requires a minimum of 15. Applicant does not require insoluble fiber, Ringe does. Ringe does not teach the method of consuming the semisolid and/or solid with a liquid to hydrate the fiber. Therefore, applicant's claim shows novel physical structure and is unobvious and clears Ringe under Sec. 102 and 103.

Claim 73 teaches at least one additional fiber can be added. Ringe teaches fibers can be added but the soluble to insoluble fiber ration must be 1 to 5:1. Applicant has no soluble to insoluble ratio restrictions, nor the requirement of an insoluble fiber. These differences and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

Claim 74 teaches a variety of additional ingredients can be added for health benefits or to reduce toxin exposure including vitamins, minerals, coenzymes, antioxidants, plant polyphenols, electrolytes , herbs, etc. can be added but are not necessary as applicant's invention does not cause vitamin and mineral deficiencies. Ringe teaches vitamins and minerals are needed to prevent vitamin and mineral deficiencies that are caused by the fiber in his invention. Ringe teaches these vitamins and minerals are a replacement, not as a method of treating or reducing risks of various diseases. These differences, type and ratio of fibers needed, and the fact that applicant is a minimum of 7 grams of fiber per serving proves that applicant's structure is novel and unobvious over Ringe and clears Ringe under sections 102 and 103.

### **THE ALLOWABLE CLAIMS UNDER 35 U.S.C 102(b) AND 103 (a).**

The office action stated that independent claim 64 and dependent claims 28,32,33, 38,and 39 were allowable under 35 U.S.C 102(b) and 103 (a).

Claim 64 is currently amended is a means claim showing the composition of the nutritional supplement and a means of administering at least 7 grams of fiber in a liquid beverage form.

Claim 28 is currently amended to remove markush groups for clarity purposes. Applicant previously tried to highlight the fact that the invention can exist as a zero calorie beverage.

Claim 32 was previously presented and unchanged. It shows at least one antioxidant could be added to the invention.

Claim 33 was previously presented and unchanged. It shows at least one tea could be added to the invention.

Claim 38 is currently amended to remove markush groups for clarity purposes. Applicant previously tried to highlight the fact that the invention can exist as a zero calorie beverage.

Claim 39 is currently amended to show the semisolid and solid food product forms the invention can exist as. Powders have been added and wafers and dog bones have been removed. Applicant has also removed the markush groups for clarity purposes. Applicant previously tried to highlight the fact that the invention can exist as a zero calorie beverage.

## **FURTHER INFORMATION FOR EXAMINER**

Applicant ran a search on 8/16/04 “ fiber and toxin” to determine if any prior art exists for applicant’s claim of using applicant’s invention to limit toxin exposure of ingested toxins. Applicant could find no prior art that was in any way similar or relevant to applicant’s invention or method. Applicant found no matches for “dietary fiber” and “ingested toxins”.

Applicant ran a search on 8/16/04 for “dietary fiber” and “high sensitivity C reactive protein” and came up with no matches. Applicant ran a search for “high sensitivity C reactive protein” and had 4 matches, none of them teaching anything about fiber or that fiber can reduce high sensitivity C reactive protein or cardiac inflammation.

## CONCLUSION

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. All claims recite novel and unobvious subject matter over Ringe. To review, Ringe teaches ready to eat cereal that is organoleptically pleasing, a method to make it and a method to lower total serum cholesterol in humans only if they follow a low fat, low cholesterol diet.

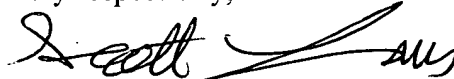
Applicant teaches a nutritional supplement that is an ultra-high fiber (at least 7 grams per serving) supplement comprising guar, oat, psyllium and a flavoring agent. Applicant is entirely different from Ringe, and has given numerous arguments on how Applicant is novel over Ringe and clears Ringe under Sec. 102. Applicant has provided numerous arguments above showing that applicant has novel structure and is unobvious over Ringe under Sec. 103. Applicant teaches dramatic health benefits including dramatic easy weight loss, weight loss without the need for diet and exercise, dramatic and unexpected benefits in LDL, HDL, triglycerides, lipoproteins, homocysteine and high sensitivity C-reactive protein levels and the ability to limit toxin exposure from ingested toxins. Applicant’s novel structure requires only 3 specific fibers. **Applicant does not require insoluble fiber, or Ringe’s ratios, and percentages.** Applicant’s invention could not have been anticipated by Ringe, as applicant does not follow Ringe’s teachings, elements, ratios, or percentages that are required to make a high fiber supplement that is organoleptically pleasing. Applicant’s serving size of fiber is a **minimum of 7 grams**, and requires no insoluble fiber. Applicant’s novel structure allows a **minimum** of 7 or more grams of fiber to be administered safely and easily to a mammal without danger or need for nutrient supplement. Applicant prefers administration with a beverage, pudding, or snack bar.

Furthermore, applicant can be made into a zero calorie food product. Applicant respectfully believes he has diligently responded to all issues in the office action. Therefore applicant submits that this application is now in condition for allowance, which applicant respectfully solicits.

### **CONDITIONAL REQUEST FOR CONSTRUCTIVE ASSISTANCE**

Applicant has made diligent effort to amend the claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason, the Examiner believes that the claims of this application are not yet in full condition for allowance, applicant respectfully requests his constructive assistance and suggestions pursuant to the spirit of MPEP Sec. 2173.02 and 707.07. This will enable the undersigned to place this application in fully allowable condition as soon as possible and without the need for further proceedings. Applicant authorizes the Examiner to make any needed minor corrections or changes.

Very respectfully,



Scott Levine MD

7350 Sandlake Commons Blvd. Ste. 2215

Orlando, Florida 32819

407-363-1515; Fax 407-363-9538

### **Certificate of Mailing**

I hereby certify that this correspondence, and attachments will be deposited with the United States Postal Service by First Class Mail, postage prepaid, in an envelope addressed to Commissioner of Patents, Washington DC 20231 on the date below.

Date: Aug., 20, 2004

Inventor's Signature



Scott D. Levine M.D.